IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS

JOSHUA WILSON, THOMAS BLANKENSHIP, STEVEN BROWN, KARYN CHRISTEN, MICHAEL DOUGHTY, SUMMER FIELDS, DERRICK GIBSON, MICHAEL GROOTHOUSEN, CARLEY GROSS, JUSTIN KING, RYAN MADIGAN, BRITTANY PUCKETT, BENJAMIN WALKER, SCOTT WELLS, for themselves and all others similarly situated,	§	
and	§	**No. 4:22-cv-438 ALM**
MEMBERS OF THE ARMED FORCES FOR LIBERTY, an unincorporated association,	§	**FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**
Plaintiffs	§	
v.	§	
LLOYD AUSTIN, in his official capacity as Secretary of the U.S. Department of Defense, U.S. DEPARTMENT OF DEFENSE,	§	
ROBERT CALIFF, in his official capacity as Commissioner of the U.S. FOOD AND DRUG ADMINISTRATION, and	§	
XAVIER BECERRA, in his official capacity as Secretary U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,	§	
Defendants	§	

TABLE OF CONTENTS

EXHIBITS

EXHIBIT 1: Jan. 10, 2023 Secretary Austin Rescission Memo

EXHIBIT 2: Nov. 30, 2021 Secretary Austin Supp. Memo

EXHIBIT 3: Sept. 14, 2021 Pfizer/BioNTech Interchangeability Directive

EXHIBIT 4: May 3, 2022 Moderna Interchangeability Directive

EXHIBIT 5: Rachel Saran MAFL Plaintiffs Declaration

EXHIBIT 6: Oct. 18, 2022 COL Rans Declaration

EXHIBIT 7: Aug. 22, 2022 COL Rans Declaration

EXHIBIT 8: Aug. 23, 2021 Purple Cap COMIRNATY® Package Insert

EXHIBIT 9: May 19, 2021 Grey Cap COMIRNATY® Package Insert

EXHIBIT 10: Aug. 18, 2022 Sen. Johnson Letter to DOD, FDA, and CDC

EXHIBIT 11: June 1, 2022 COL Rans Declaration

EXHIBIT 12: Nov. 29, 2022 MSGT Kupper Declaration

EXHIBIT 13: Sept. 15, 2022 Congressional Letter to Secretary Austin

EXHIBIT 14: Feb. 28, 2023 House Armed Services Committee Hearing Transcript

EXHIBIT 15: Feb. 27, 2023 DOD Under-Secretary Cisneros Response to HASC

EXHIBIT 16: Jan. 31, 2022 Moderna EUA Reissuance Letter

EXHIBIT 17: Oct. 21, 2021 Marks Declaration

Plaintiffs, by and through the undersigned counsel, hereby complain and allege the following:

INTRODUCTORY STATEMENT

1. On August 24, 2021, Secretary of Defense Lloyd Austin, III issued the COVID-19 vaccine mandate for the Department of Defense ("DOD") ("DOD Mandate"), which was implemented shortly thereafter by each of the Armed Services (collectively, the "Military Mandates").

2. On December 23, 2022, the DOD Mandate was "rescind[ed]" by Section 525 of the FY2023 National Defense Authorization Act (the "2023 NDAA"), which was enacted into law by veto-proof majorities in the House of Representatives (350-80) and the Senate (83-11) and signed into law by the Commander-in-Chief, President Biden.

3. Congress expressly chose the term "rescind" rather than more customary language, such as "repeal" "amend" or "modify", in order to inform and direct the DOD and the courts that the end of the mandates should have legal retroactive effect, rendering the DOD Mandate null and void *ab initio*; eliminating the legal basis for the Military Mandates and any orders issued pursuant thereto; and restoring all adversely affected service members to the position they would have been in the absence of the unlawful mandates.

4. Congress' directive to rescind the mandates removes any deference to military judgments or interpretation because the relationship between the DOD and all service members is ultimately contractual.[1] In adopting the mandate, Secretary Austin unilaterally and unlawfully

[1] The advent of the All-Volunteer Force in 1973 after the Country fractured over the Military Draft during the Vietnam War changed the legal regime for military service. After the President signed the Military Selective Service Act (particularly the stricken provisions of the prior §3815) into law, Secretary of Defense Melvin Laird famously announced on January 27, 1973: "The Armed

altered the contractual terms of service; Congress' rescission of the mandate voided that unlawful change. Rescission requires the military to restore the pre-Mandate *status quo ante* and return service members substantially to the position they would have been but for the unlawful mandates and any adverse actions taken to enforce or punish non-compliance with the mandates.

5. Congress has exercised its plenary authority under Article I, Section 8, cl. 12-14 of the U.S. Constitution to raise and regulate military forces. Where Congress has given an express directive to the military and dictated the remedy, there is no room for military discretion. The principal question before this Court—what does "rescind" mean?—is a purely legal question of statutory interpretation for which the Court need not defer to military expertise or previously asserted policy goals that Congress and the Commander-in-Chief set aside in the 2023 NDAA.

6. On January 10, 2023, Secretary Austin issued a memorandum that formally rescinded the August 24, 2021 DOD Mandate, *see* Ex. 1, but retained existing vaccination policies and restrictions and adopted a *de facto* mandate by directing commands to take vaccination status into account in making assignment, deployment, and operational decisions. Military Defendants have stated they will take corrective actions for currently serving service members, but to date have taken what appears to be *ad hoc* corrective actions with respect to Plaintiffs and other putative class members.

7. On February 28, 2023, the Under-Secretaries for the DOD and the Armed Services testified before the House Armed Services Committee that, notwithstanding Congress' rescission of the mandates: the mandates and all orders issued and adverse actions taken thereto were lawful;

Forces henceforth will depend exclusively on volunteer soldiers, sailors, airmen and Marines. Use of the draft has ended." The Plaintiffs, and all members of the Armed Forces, are volunteers to whom the DOD made legally enforceable promises, i.e. *contracted with them*, in return for their service under specific terms.

that any service member who failed to comply with such orders had disobeyed a lawful order in violation of the Uniform Code of Military Justice ("UCMJ"); that such service members may still be involuntarily discharged or prosecuted under the UCMJ; and that they will not order reinstatement, compensation, or restoration of emoluments for discharged service members or others whose careers were harmed by the Mandates.

8. Plaintiffs bring this action to challenge Defendants' unlawful implementation and enforcement of the now-rescinded mandates; their post-Rescission ratification, retention, and enforcement of the unlawful mandates and orders issued pursuant thereto; continued threats and efforts to enforce and punish service members for non-compliance with the now-rescinded mandates; their refusal to restore Plaintiffs and other service members to the pre-Mandate *status quo ante*; their failure to irrevocably and completely eradicate the legal effects of the rescinded mandates; and other agency actions to implement the mandates that remain in place.

9. The August 24, 2021 DOD Mandate directed that only products licensed by the Food and Drug Administration ("FDA") and labeled in accordance with federal law may be mandated. Because Military Defendants did not have any FDA-licensed products when the mandate was adopted, on September 14, 2021, the DOD directed that unlicensed Emergency Use Authorization ("EUA") products were legally interchangeable with, and should be mandated "as if" they were FDA-licensed products. Military Defendants imposed the full range of punitive and coercive measures for non-compliance, despite the fact that compliance was impossible due to the unavailability of FDA-licensed products and that mandating EUA products is expressly prohibited by federal law, 10 U.S.C. § 1107a.

10. The FDA engaged in series of illegal and deceptive actions to provide legal cover for the Biden Administration's unlawful federal mandates, most of which have been struck down

or are currently enjoined nationwide, including the vaccine mandates of three of the four Armed Services. These FDA legal actions included, but are not limited to, (1) a finding in a footnote that, due to the unavailability of FDA-licensed products, EUA and FDA-licensed products could be used "interchangeably" ("FDA Interchangeability Guidance"), a finding expressly foreclosed by the Public Health Safety Act ("PHSA"); (2) FDA's unlawful waiver of statutorily mandated, non-waivable labeling requirements for licensed vs. unlicensed products; and (3) waiving recipients' statutory right to be informed of their right to refuse EUA products (the "FDA Waivers"). The combined effect of the FDA Interchangeability Guidance and FDA Waivers was to grant the legal benefits of licensure to "legally distinct," **unlicensed** EUA products, circumventing federal laws governing FDA review, approval, and labeling of FDA-licensed products.

11. Plaintiffs are a group of service members on active-duty or the Reserves, including members from each branch of the military departments (but not the Coast Guard under DHS), who were subject to the Military Mandates. All plaintiffs have been subjected to adverse employment actions and discipline; most have been denied their constitutionally protected religious liberties; and many have involuntarily separated or discharged, commenced the separation process, or would have been discharged already but for a series of nation-wide injunctions granted against the Air Force, Navy and Marine Corps for systematic violations of religious liberties.

12. The named Plaintiffs, including the unincorporated association formed for this litigation, "Members of the Armed Forces for Liberty" (hereinafter "MAFL"), file this lawsuit on behalf of themselves, the members of MAFL, and of the class and sub-classes of similarly situated persons that they represent.

13. The class of plaintiffs includes all members of the combatant forces (*i.e.*, Air Force, Army, Marine Corps and Navy), Active, Reserve, and Guard, who are and have been subject to

the Military Mandates and who, post-Rescission, suffer from pre-Rescission adverse actions and the threat of continued enforcement, punishment or discriminatory treatment due to past non-compliance or their unvaccinated status ("DOD Mandate Class" or "DOD Mandate Plaintiffs").

14. The class includes the sub-class of those class members who have already been infected with, and recovered from, SARS-CoV2 ("Covid-19"), and therefore have documented and demonstrable immunity to the virus (the "Natural Immunity Sub-Class" or "Natural Immunity Plaintiffs").

15. By rescinding the mandates, Congress rejected the Military Defendants' legal positions in this litigation and its asserted national security and military readiness justifications. Congress has now answered the central questions previously before this Court: Are the Military Mandates are lawful and may service members now be punished for non-compliance?

16. In the 2023 NDAA, Congress said "no" to both. That should be the end of the story and this case. Yet, as explained below, Military Defendants have refused to comply with Congress' command and continue to impose, enforce and give legal effect to the rescinded mandates.

17. This case is not moot, as Defendants' claim, because the legal effects of the rescinded policies live on after Rescission. Defendants' now claim the mass inoculation policy a victory—"mission accomplished"—and rush to get pending cases dismissed as moot before courts can reach the merits regarding previous decisions that in carrying out the mandates, DOD systematically and willfully violated service members' rights. This Court and the judiciary more generally must hold them accountable through declaratory judgments finding that these actions were and are unlawful; otherwise, they will be emboldened to continue to illegally mandate experimental drugs and treatments in the belief that they can achieve 98% or 99% compliance with their unlawful goal before Courts or Congress can act. This is the third time this has happened in

32 years between the experimental (and unlicensed) Gulf War drugs and vaccines of 1989-90, to the investigational (and unlicensed) anthrax vaccine of 1999-2002 to the EUA mRNA (unlicensed) gene therapy products of 2021-2022.

18. Plaintiffs file this action, on behalf of themselves and similarly situated class members, seeking injunctive and declaratory relief and request that this Court:

(1) Declare that Congress' directive to "rescind" the Military Mandates means that the August 24, 2021 DOD Mandate is null and void *ab initio*, is no longer a lawful order, and cannot provide the legal basis for any subsequent orders issued pursuant thereto;

(2) Declare that the 2023 NDAA Rescission requires that the DOD and Armed Services restore Plaintiffs and other service members to the pre-Mandate *status quo ante* and return them to the position in which they would have been absent the rescinded mandates;

(3) Declare that vaccination orders issued pursuant to the now-rescinded mandates are not lawful orders and are instead legal nullities;

(4) Declare that Plaintiffs' non-compliance with such vaccination orders, or others based on the now-rescinded mandates, cannot constitute disobeying a lawful order or be used as the basis for discharge, punishment, or other adverse actions;

(5) Declare unlawful and enjoin any discharge, UCMJ punishment or prosecution, or other adverse personnel action taken based on violations of the now-rescinded Military Mandates;

(6) Order the Military Defendants to restore Plaintiffs to the pre-Mandate *status quo ante* and to return them to the position in which they would have been absent the unlawful mandates;

(7) Declare unlawful, vacate and enjoin the DOD Interchangeability Directives;

(8) Declare unlawful and enjoin the mandate of any EUA product without the Presidential waiver provided under 10 U.S.C. § 1107a;

(9) Declare unlawful, vacate and enjoin the FDA Interchangeability Determination;

(10) Declare unlawful, vacate and enjoin the FDA Waivers of mandatory statutory labeling and informed consent requirements; and

(11) Award attorneys' fees, costs, and any other appropriate relief in the Court's discretion.

19. Plaintiffs seek this relief pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702 and 705; the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 & 2202; and the All Writs Act, 28 U.S.C. § 1651.

PARTIES

20. Plaintiffs are active-duty or reserve duty service members who were subject to the Military Mandates, the DOD Interchangeability Directives, and the other challenged agency actions and remain subject to punishment or other adverse actions for non-compliance with the now-rescinded mandates.

21. All Plaintiffs have suffered some form of adverse employment action for not taking the mRNA shots, even if the Plaintiffs availed themselves of the Defendants' own written policies for exemption or accommodation. Some members were forced into early retirement; some had separation proceedings or were in that process, others were discharged, or members of the Reserve involuntary transfer into the inactive reserve. Many had separation proceedings halted by class-wide injunctions against the Air Force, Marine Corps, and Navy; several of the Plaintiffs served during the time when the previous anthrax vaccine mandate was subject to a nation-wide injunction and/or prohibited pursuant to a consent decree regarding the first EUA vaccine.

22. Plaintiff Staff Sergeant ("SSG") Steven Brown was a cryptolinguist in the U.S. Army on active duty with the 173rd Infantry Brigade Combat Team (Airborne) at Caserma Del Din, Vicenza, Italy. His domicile is Plymouth, MA. SSG Brown graduated from the Defense Language Institute (DLI) in Levantine Arabic (2015) and Russian (2019) and has two Associate's degrees. After graduating the Levantine Arabic course, he served as a Special Operations Team-Alpha (SOT-A) Team Member from 2016 – 2018. During this time, he deployed once to Africa in an E-7 billeted position leading a SOT-A Team in support of an Operational Detachment Alpha

(ODA). SSG Brown did not request any exemption from the mandate; he did, however, insist that he receive only a "fully" FDA approved shot in accordance with the SecDef's now-rescinded order.

23. For refusing an EUA vaccine and explicitly asking for the FDA approved vaccine, SSG Brown was categorized as a "vaccine refusal," was negatively counseled and flagged on Sep. 29, 2021, barring him from reenlistment and any favorable action to include awards, tuition assistance, and Army schools. He received a General Officer Memorandum of Reprimand (GOMOR) from the USAG Commanding General, Major General Andrew Rohling, on Nov 4, 2021 and filed a rebuttal reiterating his position on Nov. 9, 2021. Major General Rohling ordered the permanent placement of the GOMOR in my Army Military Human Resource Record on Jan. 19, 2022, effectively ending any hope for SSG Brown's continued career in the Army. Despite this, SSG Brown continued to support operations in Ukraine as a Russian cryptolinguist. Because SSG Brown could not re-enlist, promote, obtain any favorable actions, he left service at the end expiration if his enlistment. He is no longer in the Army or DOD. The GOMOR remains in his Army record and he has had to report it to multiple potential employers when asked.

24. Plaintiff Major Joshua Wilson was an F-16 pilot in the Air National Guard, but now flies the T-38 trainer as an instructor pilot at the 192d Fighter Wing at Langley AFB, VA. He is domiciled in McKinney, TX, because in his day job, Major Wilson is a pilot for American Airlines. He was commissioned in December 2002 and has served honorably for over 19 years in 3 combat coded airframes, with nearly 500 combat hours and 2 tours to Iraq. For the last 5 years in the Guard, he has served as a mission commander and instructor pilot training the next generation of American fighter pilots.

25. Major Wilson submitted a medical exemption request in response to the COVID shot mandate because he has a documented allergy to the contents of the shots, a prior asymptomatic infection for Covid-19 with documented antibodies, and potential for clotting due to vein anatomy and a prior surgery. Two different medical doctors have recommended Major Wilson *not* get an mRNA shot. Notwithstanding all of this, he has been told that he will likely be separated for declining to take the mRNA "vaccines." Major Wilson is currently coded as a "refusal" even though his medical exemption paperwork is still being "processed." Major Wilson's allergy waiver has usually been handled "in-house" and renewed annually without issue, but because it involves the Covid Vaccine, it has higher visibility and can no longer be handled locally. Major Wilson has been told he needs to enter a medical evaluation for suitability for service, quit, or be forced out. There were no other options given.

26. LCDR Michael Groothousen, U.S. Navy Reserve, originally enlisted in December 1998 in the VA Army National Guard as an Air Defense Artilleryman. He is domiciled in Portsmouth, VA. In May of 2000, LCdr Groothousen was discharged from the VA NG to attend the U.S. Naval Academy. After graduation in 2004, LCDR Groothousen was commissioned, attended flight training, and became a rotary-wing naval aviator. LCDR Groothousen was assigned to his fleet squadron, HSL-42, where he deployed to Operation Iraqi Freedom and received an Air Medal (Individual Award) for combat missions in theater. He was later selected to be a company officer at the Naval Academy and completed his Master's in Leadership Education and Development in 2011, serving 3 years as a Company Officer at Annapolis.

27. LCDR Groothousen left active duty and transitioned to the Naval Reserve in 2016 and has honorably served in the military a total of 19+ years. He currently is assigned to Naval Warfare Development Center, Detachment 101, as the Assistant Operations Officer and Training

Officer. LCDR Groothousen is a cancer survivor and has had a medical history of Bell's Palsy, migraines, and elevated blood pressure, so he submitted a *permanent* Medical Exemption (ME) request to the Covid-19 mRNA vaccines in coordination with his civilian flight surgeon, Dr. Mimi Peak. LCDR Groothousen concurrently submitted a *temporary* ME request because he is also a member of a clinical study being conducted by the Uniformed Services University of Health Sciences (USUHS). In Nov. 2021, LCDR Groothousen and his Commander were told by Naval Operation Support Center staff that his *temporary* ME request was approved until the USUHS study's end (in Sep. 2022). In Jan. 2022, however, he learned that his *permanent* ME had never been submitted and he was subsequently ordered in writing to be vaccinated by a local Navy doctor, CDR Alband, USN, who has never even met, much less treated, LCDR Groothousen. When LCDR Groothousen asked about his *temporary* ME approval (for being in the USUHS study) he was told that it was "no longer in effect" and would need to be resubmitted. LCDR Groothousen has also had a documented case of Covid-19 in January 2021. He was informed that none of this would affect his requirement to receive the Covid-19 shot.

28. Plaintiff COL Karyn L. Christen was a command pilot in the U.S. Air Force Reserve with a TS/SCI clearance and over 2,300 flight hours. She was also the Deputy of the Commander's Action Group, JRB Fort Worth, Texas. Colonel Christen is domiciled in Flower Mound, Denton County, TX, and is a distinguished graduate of the U.S. Air Force Academy (1995). She was forced to retire after her 3 year AGR tour was curtailed to one year because she was unvaccinated, despite having submitted a religious accommodation request and having been stratified as the #1 stratified Colonel on her last several performance reports, including the final one (while she was unvaccinated) before she was forced to retire by the Air Force's curtailment of her orders.

29. Plaintiff LtCol Summer Fields is a staff officer in the U.S. Air Force Reserves, originally enlisted, she eventually became a pilot in 1997-1998. As a Field Grade Officer, LtCol Fields was retrained to fly the RQ-4 Global Hawk, supporting combat missions and humanitarian and disaster relief missions. LtCol Fields became the Director of Operation for the 13th Reconnaissance Squadron at Beale AFB from 2013-2018 and then retained command in August 2018 until August 2020. During the beginning of the pandemic, LtCol Fields was the squadron commander and continued to execute worldwide missions and fly the RQ-4. In December 2020, Lt Col Fields moved to a staff position at the 10th AF and was asked to backfill as the executive officer to the 2-star Commander. Shortly after, she was asked to be the Director of Staff (DS) for 10 AF. LtCol Fields applied for the job and was given a temporary job offer in September 2021. By the time the DS position was ready to be filled, however, the COVID-19 vaccine mandate was handed down and Lt Col Fields was no longer considered for the position. The position was temporarily given to someone else, then advertised again as open, because LtCol Fields filed an RAR in response to the vaccine mandate. Her initial RA request was denied with the LtGen acknowledging her sincerely held beliefs, but denying the request based on the "compelling interest of the AFR" that neither the General, nor any of LtCol Fields superiors, could articulate to her. Since then, LtCol Fields has tested positive for COVID-19 antibodies in January 2022.

30. Plaintiff Capt. Ryan Madigan is a C-5 instructor pilot in the U.S. Air Force Reserve, is a C-5 Galaxy pilot serving at the 68th Airlift Squadron at Joint Base San Antonio (JBSA), Lackland, TX. Captain Madigan serves as both a traditional Reservist and a full-time Air Reserve Technician. Captain Madigan is domiciled in southern Texas. In his "other" job, Captain Madigan flies the Boeing B777 for Federal Express. Captain Madigan was commissioned in the Air Force in 2011, graduated from pilot training in 2013, and has more than 1500 hours in the C-5 Galaxy

since. He has twice been named Operations Group Flight Commander of the Quarter (Q1 and Q4 of 2021).

31. In Oct. 2021, Capt. Madigan submitted a Religious Accommodation Request (RAR) from the Covid-19 mandate. He was notified it was denied on Nov. 18, 2021, and given 72 hours to appeal, despite the fact that he was not on any kind of military orders or status at the time. Nevertheless, he submitted his appeal on time and has not had a response. In the meantime, despite being the Group Flight Commander of the Quarter for Q4 and having an RAR appeal pending, Captain Madigan was grounded from all flying by his command on Dec. 3, 2021 – to include flying simulators. As a result, Captain Madigan is no longer current in the C-5, although he has continued to fly the B777 for FedEx all over the world, without regard to his vaccination status. Captain Madigan has asked for his grounding in writing, but his command refuses to put the grounding order to paper. Capt. Madigan also caught Covid-19 in Jan. 2022 and returned to work a few weeks after his quarantine period. Plaintiff Major Ryan Madigan was placed on No Points No Pay status for 5 months, which was then followed by a 6-month period in which he was only able to participate minimally. He was formally grounded from flying and lost his qualification in the C-5, eliminating his role in the squadron. He will unlikely be able to promote to O-5 due to his lacking Officer Performance Reports as he was barred from doing his job. He has since submitted his resignation from the Air Force, which will take effect in July 2023

32. Plaintiff MAJ Justin King, U.S. Marine Corps, is a KC-130J Aircraft Commander currently stationed at MCAS Cherry Point, NC. He is domiciled in Gilmer, Upshur County, TX. Major King was commissioned in 2009 after his graduation from the U.S. Naval Academy. Upon completion of flight training, MAJ King was initially stationed at Cherry Point, as well. After his first tour, he was competitively selected for the Naval Postgraduate School in Monterey, CA,

where he graduated with distinction with an M.S. in Systems Technology. He received the Award for Academic Excellence and subsequently received orders for Marine Corps Systems Command. Upon completion of his tour at SYSCOM, Major King returned to the cockpit and flying duties at MCAS Cherry Point.

33. MAJ King submitted an RAR in response to the Covid Vaccine Mandate. After he submitted his RAR, MAJ King was placed in a non-deployable status. Despite that, in March 2022, he was sent from Cherry Point to Twenty-nine Palms, CA for a Service-Level Training Exercise for seven weeks. This exercise is supposed to mimic a real deployment, including living in close-quarters with other Marines. MAJ King was told he had to go due to staff shortages at his command. In Jan 2022, he tested positive for COVID at a military medical facility with the results included in his medical records. A few weeks later, he tested positive for anti-bodies (test conducted at Harris Teeter pharmacy) and T-cells (test completed by T-detect), indicating natural immunity. MAJ King received an initial denial from the Deputy Commandant, Manpower & Reserve Affairs (DC, M&RA) on December 2, 2021 (dated November 29, 2021). The denial contained many inaccurate statements that were thoroughly addressed in his appeal. He appealed the initial denial on December 15, 2021.

34. Plaintiff LT Thomas P. Blankenship is a Surface Warfare Officer in the U.S. Navy, currently serving in Newport, RI, at the Surface Warfare Officer School. LT Blankenship enlisted in 2000 and since then has served on nuclear deterrent sea patrols on submarines, multiple sea deployments on an Arleigh Burke class guided missile destroyer, as well as a deployment on a Ticonderoga-class guided missile cruiser. LT Blankenship is domiciled in Richardson, Collin County, TX. In 2018 he was selected to redesignate and serve as a Surface Warfare Officer (SWO) and has been a Naval Officer for 8 years. Since 2020, Lieutenant Blankenship has mentored and

instructed hundreds of Naval Officers en route to their first commands after SWO School. In September 2021, Lieutenant Blankenship submitted an RA Request in response to the COVID mandate and in November 2021 it was denied. The denial contained several inaccurate statements which he corrected in his appeal. In December 2021 LT Blankenship had a documented case of COVID-19 and subsequently tested positive for antibodies, all of which was included in his appeal which he filed in January 2022 and is currently pending. Throughout the pandemic and to the current day, LT Blankenship has continued to be in contact with hundreds of students to train them for their upcoming missions, traveled for official work or personal reasons with no issue without the shot.

35. Plaintiff Major Benjamin D. Walker is an F-16 Fighter Pilot, currently serving as a T-38C Instructor Pilot in the United States Air Force. Major Walker is stationed in Wichita Falls, Texas, on his final expected assignment in the Air Force after 21 years and 9 months of service. Major Walker was commissioned in the USAF in June 2004 from the United States Air Force Academy. He was deployed to Iraq for Operation Iraqi Freedom, where he flew 56 combat missions. He was subsequently hand-picked by his command to deploy to Afghanistan for Operation Enduring Freedom for the first USAF F-16 deployment to that theater. Following that assignment, Major Walker spent one-year unaccompanied tour in Korea as an F-16 pilot patrolling the Korean DMZ and supporting U.S. military operations in the Pacific Theater.

36. In 2015, wanting to reunite with his family, Major Walker was selected for orders to Sheppard Air Force Base in Wichita Falls, Texas, as part of the 14-nation Euro-NATO Joint Jet Pilot Training Program (ENJJPT), where he eventually came to be in charge of – the "chief" of – the "check" section, responsible for ensuring all students meet the standards for the supersonic jet trainer, the T-38C Talon. On September 17, 2021, in response to the DoD Vaccine Mandate, Major

Walker submitted a Religious Accommodation Request in accordance with his strongly held Christian beliefs. Since then, he has received a designation in his personnel file as restricted from receiving Permanent Change of Station (PCS) orders, as well as his medical records marked that he has "refused" the vaccine. He has been grounded from flight duties and had his local security clearance suspended. Major Walker was ordered and had to undergo a command-directed urinalysis and mental health evaluation after his RAR submission. Major Walker was also ordered out of the operations building in order to keep "good order and discipline" by keeping away "dissenting opinion" from the general training population of ENJJPT. In January 2022, Major Walker tested positive for antibodies and in February 2022 tested for T-cells that recognize COVID-19 vital proteins. Major Walker's RAR was denied on Feb. 9, 2022, and he appealed within the 5-day window on Feb. 14, 2022. He received his RAR appeal denial from the Air Force Surgeon General's office on March 21, 2022, and ordered to take the vaccine within 5 days.

37. Plaintiff Major Carley Gross is a KC-135R/T Pilot and Flight Commander in the U.S. Air Force currently serving at the 93rd Air Refueling Squadron at Fairchild Air Force Base, Spokane, WA. Capt. Gross hails from Del Rio, TX; she graduated from the Air Force Academy in May 2014. She completed Undergraduate Pilot Training in 2016 and then from 2017 until 2020 Capt. Gross flew the MQ-9 Reaper at Cannon AFB as an Aircraft Commander, with multiple tactical engagements and thousands of hours of intelligence, surveillance, and reconnaissance data. For this, Capt. Gross was selected Pilot of the Quarter once and logged 1600 combat hours. In 2020, Captain Gross changed duty stations to Air Mobility Command to fly the KC-135R/T in Washington and since has flown around the world throughout the European Command, Central, Southern, Northern, and Pacific Commands. During deployment, Captain Gross flew in combat for 4 months out of Qatar and Incirlik Airbase, Turkey, while supporting operations, including the

Noncombatant Evacuation Operation (NEO) from Afghanistan. Since then, she has received multiple awards for service including the 2020 and 2021 Squadron Company Grade Officer (SGO) of the Quarter Award, 2021 Squadron Flight Commander of the Year Award and 2022 Squadron Flight Commander of the Quarter.

38. Additionally, Major Gross is a sponsored, world class athlete. She ran NCAA Division I cross country and track and field at the U.S. Air Force Academy, and competed in collegiate Olympic distance triathlons, successfully completing three USA Triathlon Collegial Club National Championships and earning All-American status twice. In 2019, Major Gross raced at Ironman 70.3 Waco, qualifying for the 2020 Ironman 70.3 World Championships, which was delayed due to the pandemic. In May 2021, she qualified for the 2021 Ironman 70.3 World Championships but could not participate because she was deployed at the time. Major Gross also has natural immunity with a documented case of COVID-19 in August of 2020 that transformed into a rare case of "long COVID" in which she endured chest pains and pressures for several months. In June 2021, the morning of deployment, she tested positive for antibodies and in December 2021 tested positive for T-Cell immunity, 16 months after her initial infection. Major Gross continued to be subject to constant COVID testing and threatened with an LOR if her initial RAR was denied. Post-rescission, Major Gross' religious accommodation denial remains in her digital (online) personnel records (Personal Records Display Application, or "PRDA"). She is at a minimum six months behind her peers and, as a result of her treatment while unvaccinated, has missed out on nearly 8 months of temporary duty (TDY) opportunities and a critical training course. She is unlikely to catch up and upgrade from co-pilot to Aircraft Commander before her Active-Duty Service Commitment expires in 2026.

39. Plaintiff Master Sergeant (MSG) Derrick Gibson is a career counselor in the U.S. Army Reserve on active duty in the Active Guard Reserve ("AGR") program. He is assigned to the 9th Battalion, Army Reserve Careers Group, with duty assignment at Camp Robinson, North Little Rock, Arkansas. His domicile is Jacksonville, AR. MSG Gibson first enlisted in the Army in 1999 as a wheeled vehicle mechanic and deployed to Iraq in 2003, where he earned a Combat Action Badge. He has served honorably for over 23 years. MSG Gibson caught and recovered from Covid-19 in 2020. On July 19, 2021, MSG Gibson went to the base medical clinic and tested positive for Covid-19 with results showing "REACTIVE – Higher than Normal" more than a year after he initially had Covid-19. Because of this, he submitted a medical exemption in accordance with AR 40-562 on Aug. 23, 2021. By December, he had still heard nothing back, so he resubmitted his request with the written concurrence of his primary care manager (PCM). He still has not received a response to his medical exemption request as of this filing. Because of his 2 pending medical exemption requests, MSG Gibson was restricted to 100 miles of his base for official travel and had his Permanent Change of Station orders (PCS) to Fort Jackson, SC, for June 2022 were pulled.

40. Plaintiff LtCol Scott M. Wells, TX Air National Guard, is currently a Maintenance Squadron Commander serving at Fort Worth Joint Reserve Base (JRB), Texas. LtCol Wells first enlisted in the U.S. Air Force in 1992 as a C-130 Crew Chief for 4 years in the Air Force and then in the NC Air National Guard working on F-16s. In 2003, he was commissioned as a C-130H Navigator. In 2011 he transferred to the Texas Air National Guard where he still is. LtCol Wells was promoted to Chief Navigator, then promoted again to Chief of Current Operations for the 16th Air Wing at JRB Ft. Worth. LtCol Wells has deployed three times to Afghanistan and Kuwait as a Company Grade Officer, and three times to Kuwait as a Field Grade Officer in support of

Operation Enduring Freedom, Operation Freedom Sentinel, and Operation Resolute Support. He has amassed over 3300 flight hours, including 663 combat and 121 combat support hours, and been awarded the Meritorious Service Medal, 6 Air Medals, and other awards for distinguished service. On October 26, 2021, he submitted a Religious Accommodation request in response to the mandate. Despite having traveled throughout the height of the pandemic in 2020 and through 2021 unvaccinated without incident, Colonel Wells' accommodation request went unanswered. LtCol Wells has served honorably for over 30 years.

41. Plaintiff Staff Sergeant (SSgt) Brittany N. Puckett is a Survival Evasion Rescue Escape (SERE) instructor for pilots and other "high-risk" military members. She is currently stationed at Cannon AFB, New Mexico, but she grew up in, and her Home of Record (HOR) is Sanger, Denton County, TX. SSgt Puckett enlisted in 2014 and has completed 29 jump missions and led thousands of hours of instructions for aircrew. SSgt Puckett's work requires her to attend continuation training, observation trips, hands-on schooling, and other trainings, but since she submitted her Religious Accommodation Request (RAR) on September 15, 2021, she has prohibited from attending any training. She contracted COVID-19 in December of 2019 and when tested for antibodies, her results showed substantial immunity to the virus. She has since not contracted the virus despite being in close contact with positive cases. On January 28, 2022, SSgt Puckett's RAR was denied in a "drop-down menu" format with several grammatical mistakes. She appealed and is still waiting for a response. SSgt Puckett visited her base clinic immunization section to determine if there was any Comirnaty or other "fully licensed" products and was informed by the medical staff that there are no fully licensed products available, that the staff is aware that all of the products they have in stock are conspicuously labeled EUA, and that the staff are not providing the appropriate informed consent in compliance with C.F.R. Title 21 50.23

because they fear their careers and medical licenses are at risk if they do not follow through on the mandate to vaccinate everyone. SSgt Puckett is at risk of losing her retirement and having to pay back her $55,000 selective reenlistment pay because she won't take the mRNA shot.

42. Plaintiff Capt. Michael Doughty is a Cyber Warfare Officer in the U.S. Air Force Reserves, currently serving at Offutt Air Force Base, Nebraska. He is domiciled in Little Elm, Denton County, TX. Capt. Doughty first enlisted in the Air Force Reserves in July 2005 in response to the events of September 11, 2001, as an aircraft maintainer on the F-16 until 2012 when he was selected to go to Officer Training. Captain Doughty served as an Air Battle Manager from 2012-2020. In May 2020, he joined a new unit and cross-trained to become a Cyber Warfare Operations Officer. Capt. Doughty submitted a Religious Accommodation Request (RAR) in response to the COVID-19 vaccine mandate, which was initially denied, then rescinded as "in error." He was then informed to submit his RAR package for Covid-19 *only* and then submit a *separate* RAR for other vaccines, like influenza. Capt. Doughty did this, but shortly after was ordered to resubmit his package for Covid-19 (again). He was informed on the phone of the RAR's denial and given the week to appeal. At the time he was informed of the denial, Captain Doughty was a non-duty status civilian, so he was ordered to comply within a time when he was not in a military status. Captain Doughty sent an official memorandum for record (MFR) to his command on March 11, 2022, requesting an extension to the appeal timeline so that he could have time to request his original packet, review it, and seek legal counsel if necessary. This request was denied the same day, and he was ordered to turn in his appeal by March 15, 2022, which he did. Captain Doughty has a documented case of COVID-19 in January 2022 and was tested positive for antibodies on February 28, 2022, and he has still not received a response to his appeal. During the pandemic, Capt. Doughty completed a 4-month temporary duty assignment at the U.S. Strategic

Command (for which he received a Joint Service Commendation Medal), attended and graduated the six-month Cyber Warfare Training school, graduated a two-month Cyber Defense Analysis Initial and Mission Qualification Training, and traveled across the country for multiple trainings, all prior to the mandate and during the height of the COVID-19 pandemic.

43. Members of the Armed Forces for Liberty ("MAFL," or "the Association") is an unincorporated association formed solely for the purpose of this litigation. It is comprised of 510 members of the Armed Forces (in addition to the 14 named plaintiffs), from all branches of the services (except the Coast Guard), active duty, Reserve, Guardsman, and from across the range of enlisted and officer ranks, up to Colonel (O-6). The common legal issue all members of the Association share is that they are all subject to the illegal enforcement of Defendant Austin's Covid-19 Mandate and the Defendant FDA's illegal regulatory actions and inactions regarding mRNA EUA products.

44. The named Plaintiffs and members of MAFL represent the DOD Mandate Class or DOD Mandate Plaintiffs, which is the class of members of the Armed Forces who are similarly situated to the named Plaintiffs and who are subject to the mandatory declarations and orders of the Department of Defense in relation to the compulsory use of Covid-19 vaccines. Certain Plaintiffs also represent the Natural Immunity Sub-Class or Natural Immunity Plaintiffs, which includes members of the Armed Forces who are similarly situated to the named Plaintiffs and who have had a documented case of Covid-19 and recovered from it.

45. Defendant DOD is a Department of the United States Government. It is led by the Secretary of Defense, Lloyd J. Austin, III.

46. Defendant Department of the Air Force is a Department of the United States Government. It is led by the Secretary of the Air Force Frank Kendall.

47. Defendant Department of the Army is a Department of the United States Government. It is led by the Secretary of the Army Christine Wormuth.

48. Defendants Marine Corps and Navy are under the Department of the Navy, which is a Department of the United States Government. It is led by Navy Secretary Carlos Del Toro.

49. Defendant FDA is an agency of the United States Government. It is led by Commissioner Robert Califf.

JURISDICTION AND VENUE

50. This case arises under federal law, including the Fourteenth Amendment to the U.S. Constitution, U.S. CONST., AMEND XIV; 10 U.S.C. § 1107a; the APA, 5 U.S.C. § 551 *et. seq*.; various DOD regulations, including DOD Instruction ("DODI") 6205.02, DODI 6200.02, and Army Regulation ("AR") 40-562; the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq*.; the Public Health Safety Act ("PHSA"), 42 U.S.C. § 262 *et seq*.; and FDA regulations implementing the FDCA and PHSA.

51. The Military Mandates, the DOD Interchangeability Directives, the FDA Interchangeability Guidance, FDA Waivers, and other challenged agency actions are final agency actions for which there is no other adequate remedy in a court. 5 U.S.C. § 704. These actions mark the consummation of the agency's decision-making process. Each has direct and appreciable legal and life-altering consequences for Plaintiffs and millions of other U.S. citizens.

52. To the extent that the DOD Interchangeability Directives, the FDA Interchangeability Guidance, FDA Waivers are deemed not to be final agency actions subject to APA review, this Court has jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 2201 to review and provide declaratory and injunctive relief for these *ultra vires* actions that "wholly deprive[s]

the [Plaintiffs] of a meaningful and adequate means of vindicating [their] ... rights" under federal statutes. *Rhode Island Dep't of Env't Mgmt. v. United States*, 304 F.3d 31, 41–42 (1st Cir. 2002).

53. Jurisdiction is proper in this Court under the APA, 5 U.S.C. § 702, and under 28 U.S.C. § 2201, which states that actions involving controversies with federal agencies may be pursued in any United States District Court, and under 28 U.S.C. §§ 1331 and 1346.

54. Venue is proper in this Court pursuant to 28 U.S.C. § 1402 and 28 U.S.C. § 1391(e) because a plurality of the Plaintiffs are stationed and/or domiciled in this district, and because a substantial part of the acts or omissions giving rise to their claims have occurred, are occurring, or will occur in this District.

STATEMENT OF FACTS

I. PREVIOUS MANDATES AND INFORMED CONSENT LAWS

55. The DOD has a continuous record of abusing servicemembers' rights by trick, deception, force, and sometimes by negligence, and/or by hiding such actions through destruction of evidence or classifying them in order to keep them from public purview. *See, e.g.*, IS MILITARY RESEARCH HAZARDOUS TO VETERANS' HEALTH? LESSONS SPANNING HALF A CENTURY, Committee on Veterans' Affairs, S. Prt. 103-97 (Dec. 8, 1994). From atomic veterans who were intentionally exposed to nuclear detonations in the 1940s, to the Army's (and CIA's) MKULTRA program of the 50's and 60's, to the Agent Orange carcinogenic defoliant in Vietnam, through unlicensed and experimental products – including vaccines – during the first Persian Gulf War, Congress has repeatedly had to interject itself to stop DOD from abusing American citizens turned military servicemembers. *See, e.g.*, Dale Saran, *United States v. Members of the Armed Forces*, pp. 9-29 (2d ed., 2021).

56. Prior to the first Gulf War, the DOD sought to pretreat service members with

several unlicensed, "investigational" new drugs, which under U.S. law could not be administered to military members without informed consent. The DOD successfully petitioned the FDA to establish a new rule waiving U.S. servicemembers right to informed consent. In numerous hearings in the aftermath of the Gulf War, the administration of these experimental drugs has been correlated with "Gulf War Illness" or "Gulf War Syndrome," which "debilitated over 174,000 service members." *See generally* Efthimios Parasidis, *Justice and Beneficence in Military Medicine and Research*, 73 Ohio St. L.J. 723, 732-39 & 759-60 (2012).

57. Under Article I, Section 8, clauses 12-14 of the U.S. Constitution, Congress has plenary authority to regulate the Armed Services, including protecting servicemembers from such experiments; to recognize their human rights to informed consent; and to prohibit the military from ordering or mandating them to participate in medical experiments or to take experimental treatments.

58. After extensive hearings in Congress across multiple committees documenting systemic, repeated failures by the DOD involving the health of America's all-volunteer force, including the ill-fated and disastrous anthrax vaccine, the U.S. Congress passed Title 10 U.S.C. §1107 in 1997. This statute requires that, in any instance in which the DOD sought to use any unlicensed product on members of the Armed Forces, no one short of the Commander-in-Chief could waive a servicemember's right to informed consent.

59. In 2003, the U.S. District Court for the District of Columbia issued a preliminary injunction against the DOD for mandating the unlicensed anthrax vaccine, and in 2004 that same court issued a permanent nation-wide injunction prohibiting the DOD's anthrax vaccine mandate. *See Doe v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003)("*Rumsfeld I*"), *modified sub nom. John Doe No. 1 v Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004) ("*Rumsfeld II*"), *modified sub nom. John*

Doe No. 1 v. Rumsfeld, 2005 WL 774857 (D.D.C. Feb. 6, 2005) ("*Rumsfeld III*").

60. In the middle of that litigation in 2004, Congress passed the Project BioShield Act, the first version of the current EUA statute, 21 U.S.C. §360bbb-3. Shortly thereafter, Congress also passed mirror image statute applicable to the new EUA products for the protection for servicemembers' informed consent rights, 10 U.S.C. §1107a.

61. Shortly after the EUA statute's passage, the FDA granted the first ever EUA for the anthrax vaccine. Both the DOD and FDA then jointly filed an emergency petition in the D.C. District Court to modify the permanent injunction already in place to allow the vaccine to be administered to servicemembers *solely on a voluntary basis* and prohibited any punishment for those who refused. The court modified the injunction accordingly:

> ORDERED that the Court's injunction of October 27, 2004, is modified by the addition of the following language: 'This injunction, however, shall not preclude defendants from administering [the anthrax vaccine], on a *voluntary* basis, pursuant to the terms of a *lawful* emergency use authorization ("EUA")[.]

See Rumsfeld III, 2005 WL 774857, at *1 (emphasis in original). *See also* FDA, *Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Availability*, 70 Fed. Reg. 5452, 5455 (Feb. 2, 2005) (Section IV "Conditions of Authorization").

62. Many plaintiffs – essentially any with more than 17 years of service as of the date of SecDef Austin's Memorandum – joined the military before the *Rumsfeld I* preliminary injunction, the *Rumsfeld II* permanent injunction, and/or the *Rumsfeld III* consent decree were in place, and thus were beneficiaries of these protections, and may be deemed to have been parties to these proceedings.

63. In 2008, the DOD issued DOD Instruction 6200.02 ("DODI 6200.02") the currently effective regulation governing the mandate of EUA products. Consistent with the EUA statute, 10

U.S.C. § 1107a, and the nation-wide consent decree in *Rumsfeld III*, the instruction requires that the DOD include an option to refuse an EUA product that may only be waived "if the President determines, in writing, that providing to members of the armed forces an option to refuse is not in the interests of national security." DODI 6200.02, *Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs*, ¶ E3.4 (Feb. 27, 2008).

64. DODI 6205.02 is the extant governing regulation for routine military immunizations. This instruction defines a "vaccine" and "vaccination" as:

> **vaccination**. The administration of a vaccine to an individual for inducing *immunity*.
>
> **vaccine.** A preparation that [1] contains one or more components of a biological agent or toxin and [2] induces a protective immune response against that agent when administered to an individual.

DODI 6205.02, ¶ G.2 ("Definitions"), available at: https://perma.cc/8HLA-AXQB. The first and second clause establish an identity relationship between the "biological agent" administered (*i.e.*, mRNA) and "that agent" against which the vaccine "induces a protective immune response" (*i.e.*, COVID-19 virus). The identity relationship presents a binary choice—either the agent in [1] the same as "that agent" in [2] or it is not—with no space in between for ambiguity. The mRNA shots do not "contain" a single molecule of the COVID-19 virus, and therefore the mRNA shots are not "vaccines" under DODI 6205.02

II. MILITARY MANDATES IMPLEMENTATION & RESCISSION

A. The August 24, 2021 Mandate

65. On August 24, 2021, Secretary Austin issued the DOD Mandate directing the Secretaries of the Military Departments "to immediately begin full vaccination of all members of the Armed Forces … who are not fully vaccinated against COVID-19." ECF 4-12, DOD Mandate, at 1. Mandatory vaccination would "only use COVID-19 vaccines that receive full licensure from

the [FDA], in accordance with FDA labeling and guidance." *Id.* Secretary Austin justified the mandate as necessary to "protect the Force", *id.*, and cited DOD Instruction 6205.02, the "DOD Immunization Program" (July 23, 2019), as the sole legal authority for the mandate. *Id.* To be clear, SecDef Austin's Memorandum added Covid-19 mRNA inoculations to the list of required vaccines for members of the military, which is found in the joint service publication AR 40-562, at Appendix D.

66. Each of the Armed Services issued their own mandates shortly after the issuance of the DOD Mandate. *See, e.g.,* ECF 5-9, Dept. of the Air Force, "COVID-19 Mandatory Vaccination Implementation Guidance for Service Members" (Sept. 3, 2021) (Air Force Mandate); ECF 5-12, Dept. of the Army, FRAGO 5 to HQDA EXORD 225-21 COVID-19 Steady State Operations (Sept. 14, 2021) (Army Mandate); ECF 5-10, U.S. Marine Corps MARADMINS 462/21 (Marine Corps Mandate) (Sept. 1, 2021); ECF 5-10, Dept. of the Navy, NAVADMIN 190/21 (Navy Mandate) (Aug. 30, 2021). Each of the Armed Services have issued subsequent orders implementing and modifying the initial Armed Services Mandates.

67. On November 30, 2021, Secretary Austin issued supplemental directives for Members of National Guard and Ready Reserve, which directed that unvaccinated National Guard members: (1) cannot "participate in drills, training or other duty conducted under title 32" unless otherwise exempted; (2) "no funding may be allocated for payment of duties performed under title 32" for unvaccinated National Guard members; and (3) "[n]o credit or excused absence shall be afforded to members who do not participate in drills, training, or other duty due to" being unvaccinated. *See* Ex. 2, Nov. 30, 2021 Secretary Austin Memo, at 1. As a result, tens of thousands of unvaccinated members of the National Guard and Reserves have been denied pay and benefits starting in January 2022.

B. DOD Interchangeability Directives

68. Military Defendants have had in place at all relevant times an express policy to deceive service members—orally and in writing—by stating that unlicensed, EUA products are in fact FDA-licensed products and even referring to these unlicensed products by the proprietary name—COMIRNATY® or SPIKEVAX®—that, pursuant to federal and state law, may only be used for FDA-licensed products.

69. On September 14, 2021, Assistant Secretary of Defense for Health Affairs Terry Adirim issued a memo stating that the Pfizer/BioNTech EUA product and the licensed COMIRNATY® "are 'interchangeable' and DOD health care providers should use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine," and that "DOD health care providers will use both [products] interchangeably for the purpose of " implementing the DOD Mandate. Ex. 3, Sept. 14, 2021 Pfizer/BioNTech Interchangeability Directive, at 1.

70. On May 3, 2022, the DOD issued the same directive that EUA Moderna COVID-19 vaccines were to be used interchangeably with, and "as if," they were the FDA-licensed and labeled Moderna Spikevax vaccine. *See* Ex. 4, May 3, 2022 Moderna Interchangeability Directive, at 1.

71. The Armed Services have also directed that unlicensed EUA products be used "interchangeably" or "as if" they were FDA-licensed products. For example, while the Air Force Mandate states that "[o]nly an FDA-licensed vaccine may be mandated," ECF 5-12, Air Force Mandate, § 3.1.3, it goes on to repeat the FDA's (incorrect) claim that the EUA BioNTech Vaccine is "interchangeable" with the licensed product and that "[p]roviders can use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine." *Id*.,

§ 3.1.1; *see also id.*, § 5.3.2.1 (same). *See also* ECF 4-15, BUMED Memo 6300, *Interchangeability of FDA-Approved Pfizer-BioNTech Vaccine Comirnaty and FDA-Authorized Pfizer-BioNTech Vaccine Under EUA* (Sept. 3, 2021) ("BUMED 6300"), at 1.

C. Mandate of Unlicensed EUA Products

72. Military Defendants did not possess any FDA-licensed products that could be mandated when the mandates were issued.

73. Military Defendants have in fact "mandate[ed] vaccines from EUA-labeled vials." *Doe #1-#14 v. Austin*, 572 F.Supp.3d 1224, 1223, 2021 WL 5816632 (N.D. Fla. 2021).

74. Military Defendants also adopted generally applicable policies: (1) to misrepresent that they had FDA-licensed vaccines to service members and that EUA products are instead "FDA-licensed" or describing EUA products as COMIRNATY® or SPIKEVAX®, which Plaintiffs have repeatedly confirmed were not in fact available; (2) to misrepresent unlicensed EUA products by stating that the EUA products available "are" COMIRNATY®; and (3) to punish and discharge service members like Plaintiffs who refuse to take an unlicensed vaccine, which may not be mandated. *See infra* Section VI (summarizing Plaintiffs' injuries and standing) & Ex. 5, Saran Decl.

75. Plaintiffs have repeatedly confirmed that no FDA-licensed products were available to them, rendering compliance with the DOD Mandate impossible.

76. Military Defendants did not have any FDA-licensed COMIRNATY® until at least June 2022 (*i.e.*, ten months after licensure), while consistently misrepresenting unlicensed products as FDA licensed. *See* Ex. 6, Oct. 18, 2021 Rans Decl., ¶ 4. This is an admission that Military Defendants did not have any FDA-licensed COMIRNATY® before that date.

77. Military Defendants did not have any SPIKEVAX® in their possession until

September or October 2022 (*i.e.*, more than a year after the adoption of the mandate). This is confirmed by Defendants' August 22, 2022 filing in related litigation Colonel Rans asserts that DOD could "order" SPIKEVAX®, *see* Ex. 7, Aug. 22, 2022 Rans Decl., ¶ 4, but did not state that they had even a single dose in their possession.

D. Defendants' Misrepresented Availability of FDA-Licensed Products and Expiration of All FDA-Licensed Products.

78. **Purple Cap COMIRNATY®.** Plaintiffs review of FDA and CDC records indicates that the original Purple Cap COMIRNATY® approved on August 23, 2021, which was the proximate cause for the August 24, 2021 DOD Mandate, was never manufactured or marketed in the United States. *See* ECF 4-18, Sept. 13, 2021 Pfizer Announcement, at 1 (Pfizer statement that "it does not plan to produce any product with these new NDCs [*i.e.*, for Purple Cap COMIRNATY®] and labels over the next few months."). This is confirmed by the FDA-approved package insert, which lists the "start" and "end" marketing dates as "8/23/2021", *i.e.*, it was removed from the market on the same day it received FDA approval. *See* Ex. 8, Aug. 23, 2021 Purple Cap COMIRNATY® Package Insert, at 21.

79. **Grey Cap COMIRNATY®.** The October 18, 2022 declaration of Colonel Tanya Rans provides a list of "BLA-approved, Comirnaty-labeled" vaccines, Ex. 6, Oct. 18, 2021 Rans Decl., ¶ 4, that are identified as "Pfizer Grey Cap COMIRNATY." *Id*., Ex. A. The "Comirnaty-labeled, BLA-approved" products obtained by DOD in June 2022 are from lots FW1330, FW1331, and FW1333 (the "FW Lots"). *See id*. All of the vials from the FW Lots are unlicensed, misbranded, and have now expired.

80. Official FDA records establish that each of these FW Lots were manufactured at Pharmacia & Upjohn's Kalamazoo, Michigan facility ("Kalamazoo Facility"), which was not an FDA-approved facility at any of the relevant times (*i.e.*, date of manufacture, date of lot release,

or date of order by or shipment to DOD). This is confirmed by FDA-approved Grey Cap COMIRNATY® package inserts, which are required to list FDA-approved manufacturing facilities but do not list the Kalamazoo Facility as an FDA-approved manufacturing facility. *See* Ex. 9, May 19, 2022 Grey Cap COMIRNATY® Package Insert.

81. Military whistleblowers have submitted testimony to Congress that identifies official records from the website of the Centers for Disease Control and Prevention ("CDC"), which lists the FW Lots as EUA products. *See* Ex. 10, Aug. 18, 2022 Letter from Sen. Ron Johnson to DOD, FDA and CDC, at 3.

82. The FW Lots also expired months before the mandate was rescinded. Official FDA records (lots release letters) and the FDA-approved product labels state that the expiration date is September 30, 2022 for Lots FW1330 and FW1331 and October 31, 2022 for Lot FW 1330. *See id.* at 1 (pictures of FW1331 product labeling with "09/2022" expiration date); Ex. 11, June 1, 2022 Rans Decl., ¶ 8 (vials ordered May 20, 2022 by DOD had "the latest expiration date [of] September 30, 2022").

83. The currently effective and all previous, archived versions of the Pfizer Comirnaty Grey Cap package insert state that: "Regardless of storage condition, the vaccine should not be used after the expiration date printed on the vial and cartons." *See, e.g.,* Ex. 9, May 19, 2022 Grey Cap COMIRNATY® Package Insert, at 27.

84. **SPIKEVAX®.** All available SPIKEVAX® expired and was no longer orderable on or before January 23, 2023, the deadline for Rescission of the Mandate.

E. Adverse Actions Taken Against Unvaccinated Service Members

85. Under the UCMJ, a service member who disobeys "any lawful general order or regulation," UCMJ § 892(2), Art. 92(2), faces sanctions up to a court-martial. UCMJ § 892. To

date Military Defendants have separated several thousand unvaccinated service members, and they likely would have separated tens of thousands more, including several Plaintiffs, if this had not been halted by the three class-wide injunctions against the Air Force, Marine Corps and Navy for systemic violations of the Religious Freedom Restoration Act ("RFRA").

86. Military Defendants have imposed a wide range of restrictions and taken disciplinary actions against unvaccinated service members like Plaintiffs, including: training, travel, leave/liberty, and duty restrictions; forced masking and weekly testing, both EUA medical interventions; denial or restriction of promotions; non-deployable status; negative counseling or reprimands; ineligibility for change of station or new assignments; forced early retirement; and/or removal from command. *See* Ex. 5, Saran Decl.

87. In addition to these deceptive measures, Military Defendants have employed a wide range of coercive measures to force service members to forfeit their right to refuse an unlicensed product. *See supra* Section VI (summarizing coercive measures and punishment of Plaintiffs).

III. RESCISSION OF THE MILITARY MANDATES

A. Expert Consensus That FDA-Licensed Vaccines Are Obsolete and Ineffective.

88. As early as January 10, 2022, Pfizer's CEO admitted that the mandated vaccines "offer[s] very limited protection, if any" to the then-prevalent Omicron variant. *See New COVID-19 Vaccine That Covers Omicron 'Will Be Ready in March,' Pfizer CEO Says* Yahoo!Finance (Jan. 10, 2022) (transcript of video interview with Pfizer CEO Albert Bourla), available at: https://finance.yahoo.com/video/covid-19-vaccine-covers-omicron-144553437.html (last visited Jan. 17, 2022).

89. Based on Plaintiff's review of official CDC data, the manufacturers long ago ceased production of their FDA-licensed products. Pfizer manufactured the last FDA-licensed lot in

COMIRNATY® in February 2022, and Moderna manufactured the last lot of SPIKEVAX® in April 2022. *See* Ex. 12, Nov. 29, 2022 MSGT Kupper Decl., ¶ 12.

90. The U.S. government's expert public health agencies recognized the obsolescence of the FDA-licensed vaccines at least as early as August 2022 and have abandoned the product.

91. On August 11, 2022, the CDC issued updated guidance to "no longer differentiate based on a person's vaccination status." *See* CDC, *Summary of Guidance for Minimizing the Impact of COVID-19 on Individual Persons, Communities, and Health Care Systems – United States, August 2022* at 5 (Aug. 11, 2021), available at: https://www.cdc.gov/mmwr/volumes/71/wr/mm7133e1.htm (last visited Mar. 22, 2023)

92. On August 16, 2022, the White House announced that the U.S. government would no longer purchase or provide reimbursement for the "monovalent" versions of the COVID-19 vaccines, whether EUA or FDA-licensed, and the CDC announced that the U.S. government, through HHSC, would instead purchase 175 million doses of the new "bivalent" vaccines. *See* CDC, *Fall Vaccination Operational Planning Guide* at 1 (Aug. 16, 2022). In other words, the sole customer and payor for the Mandated mRNA Products expressly adopted a policy that it would no longer purchase or provide reimbursement for the mandated, FDA-licensed products.

93. In related litigation, courts have found that Military Defendants have failed to provide any current or relevant data regarding the marginal risks and benefits of the Mandated mRNA Treatments for healthy service members under current circumstances, namely, 2022 data with respect to the currently prevalent Omicron sub-variants when 98% of other service members are fully vaccinated. Instead, Defendants have provided only "historical data from the 2020 and 2021 pre-Omicron, pre-vaccine phase" that does not "address the present state of 'the force." *Colonel Fin. Mgmt. Officer v. Austin*, No. 8:22-CV-1275-SDM-TGW, 2022 WL 3643512, at *16

(M.D. Fla. Aug. 18, 2022) ("*CFMO*").

94. The scientific evidence demonstrating the obsolescence and ineffectiveness of the FDA-licensed vaccines is too voluminous to summarize here. It should suffice to say that these facts are now so widely recognized that the mRNA vaccines were, at best, a failed experiment, and even the creators and loudest champions like Dr. Anthony Fauci, that viruses like COVID-19 have long been known to be not "vaccine preventable," even in theory. *See, e.g.,* Anthony Fauci, et al., *Rethinking next-generation vaccines for coronaviruses, influenzaviruses, and other respiratory viruses*, CELL HOST AND MICROBE at 1, Vol. 31, Iss. 2. (Feb. 8, 2023), available at: https://doi.org/10.1016/j.chom.2022.11.016 (last accessed Mar. 15, 2023).

B. Adverse Impact of DOD Mandate on Military Readiness

95. Nearly 8,500 service members have been discharged for non-compliance with the DOD Mandate, including 1,841 Army Soldiers, 3,717 Marines, 834 airmen and 2,041 Navy sailors. *See* Caitlin Doornbos, *Pentagon Ends COVID-19 Vaccine Mandate for US Troops* NY Post (Jan. 11, 2023), available at: https://nypost.com/2023/01/11/pentagon-ends-covid-19-vaccine-mandate-for-us-troops/ (last accessed Mar. 15, 2023).

96. At least 60,000 to 70,000 members of the Army National Guard, Army Reserves, Air National Guard, or Air Force Reserve were involuntarily transferred to the inactive reserves and/or denied pay or benefits.

97. On September 15, 2022, over 50 Members of Congress wrote to Secretary Austin to express "grave concern of the effect of the" DOD Mandate because, "[a]s a major land war rages in Europe our own military faces a self-imposed readiness crisis." Ex. 13, Sept. 15, 2022 Congressional Letter to Secretary Austin, at 1. They identify the DOD Mandate as the "primary cause of the [DOD]'s recruiting difficulties," which will result in the loss of at least 75,000 from

the Army alone, *id.* at 2, and effectively "disqualifies more than forty percent of the Army's target demographic from service nationwide, and over half of the individuals in the most fertile recruiting grounds." *Id.* at 2.

98. Military Defendants were fully aware of these adverse impacts, yet strongly opposed efforts to modify or rescind the mandates. The Executive Branch opposed rescission and believes that Congress's direction to rescind the mandate was a "mistake." Heather Mongilio, *Pentagon Unclear How Military Would Manage End of Mandatory COVID-19 Vaccines*, USNI NEWS (Dec. 7, 2022), https://news.usni.org/2022/12/07/pentagon-unclear-how-military-would-handle-end-of-mandatory-covid-19-vaccines (last visited Mar. 23, 2023).

99. Defendants indicating that they would continue to discriminate against the unvaccinated after rescission. Secretary of the Navy Carlos Del Toro stated in December that the repeal of the mandate will "unquestionably . . . create almost two classes of citizens in our services . . . Those that can't deploy and those that can deploy." *Id.*

C. 2023 NDAA Rescission Directive

100. The 2023 NDAA was enacted by veto-proof majorities of 83-11 in the Senate and 350-80 in the House. Section 525 of the 2023 NDAA directed Secretary of Defense Lloyd Austin, III to "rescind" the August 24, 2021 DOD Mandate. H.R. 7776, Pub. L. No. 117-263, 136 Stat. 2395 (2022)

101. On December 23, 2022, despite his previously stated vehement opposition to Rescission, President Biden signed into law the 2023 NDAA.

102. Congress intentionally used the term "rescind" rather than "repeal" to instruct Secretary Austin and the courts that Section 525 must be applied retroactively. "Rescind" is derived from the Latin "rescission", which means "an annulling; avoiding, or making void;

abrogation; rescission". BLACK'S LAW DICTIONARY at 1306 (6th ed. 1990). [2] It is normally used in the context of *rescission* of a contract, where it means to "abrogate, annul, avoid or cancel a contract;" "void in its inception"; or "an undoing of it from the beginning." *Id.* "Rescind" thus necessarily has retroactive effect and renders the rescinded contract, policy, or rule void *ab initio.* Section 525 thus reflects the determination by veto-proof majorities of Congress that Secretary Austin's Mandate was void *ab initio*. Congress has also previously used "repeal" for actions such as the controversial "Don't Ask, Don't Tell" policy.

103. *Rescission* requires the military to restore the pre-Mandate *status quo ante* and return service members substantially to the position they would have been but for the unlawful mandates and any adverse actions taken to enforce or punish non-compliance with the mandates.

D. Formal Rescission of Mandate

104. On January 10, 2023, Secretary Austin rescinded the August 24, 2021 DOD Mandate. *See* Ex. 1, Jan. 10, 2023 SECDEF Rescission Memo. In the Rescission Memo, Secretary Austin acknowledged that Section 525 applies retroactively by ordering that all separations and discharges resulting solely from non-compliance with the DOD Mandate should be halted and that all adverse personnel actions and paperwork should be corrected. *Id.* at 1. Secretary Austin further directed the Service Secretaries to cease adjudication of RARs and medical or administrative exemptions. *Id.*

105. On February 24, 2023, the DOD issued a memorandum directing DOD components to formally rescind other existing vaccination requirements and stating that the DOD would revise DODI 6205.02 to prohibit commands from taking vaccination status into account in making

[2] In the recently elected 118th Congress, "30% of House Members, and 51% of Senators, have law degrees and have practiced law." Cong. Research Service, *Membership of the 118th Congress: A Profile*, Mar. 13, 2023. Available here: https://sgp.fas.org/crs/misc/R47470.pdf

assignment, deployment and operational decisions, without express DOD approval. *See* Deputy Secretary of Defense, *Guidance for Implementing Rescission of August 24, 2021 and November 30, 2021 Coronavirus Disease 2019 Vaccination Requirements for Members of the Armed Forces* (Feb. 24, 2023), available at: https://perma.cc/3MXS-2CNR ("February 24, 2023 Guidance Memo").

106. Each of the Armed Services has issued orders rescinding that Service's mandate. Plaintiffs have provided copies of all such guidance issued through March 17, 2023 (collectively, "Armed Services Rescission Orders"). *See* Fragmentary Orders 35-38 to HQDA EXORD 225-21 (various dates); HQDA EXORD 174-23 (Mar. 7, 2023); *Army Policy Implementing the Secretary of Defense COVID-19 Vaccination Mandate Rescission* (Feb. 24, 2023); NAVADMIN 05/23 (Jan. 11, 2023); ALNAV 009/23 (Jan. 20, 2023); NAVADMIN 038/23 (Feb. 15, 2023); *Department of the Navy Actions to Implement Coronavirus Disease 2019 Vaccine Rescission* (Feb. 24, 2023); NAVADMIN 065/23 (March 7, 2023); MARADMIN 025/23 (Jan. 18, 2023); MARADMIN 109/23 (Feb. 28, 2023); ECF 135-4, Compiled Air Force Guidance Documents: *Mem. Re: Rescission of the 3 September 21 Mandatory COVID-19 Vaccination of DAF Military Members and 7 December 2021 Supplemental COVID-19 Vaccination Policy Memo* (Jan. 23, 2023); *AFR Guidance for COVID-19* (Feb. 10, 2023); *DAF Guidance on Removal of Adverse Actions and Handling of RARs* (Feb. 24, 2023); National Guard Bureau, *Mem. re: Return of Non-Federalized T32 National Guard Service Members* (Jan. 18, 2023) & *Updated NGB Official COVID-19 Travel Guidance* (Feb. 3, 2023).

E. Remaining Restrictions and Credible Threat of Enforcement and Punishment for Non-Compliance with Rescinded Mandates

107. Secretary Austin's January 10, 2023 Rescission Memo retains existing restrictions and either retains or adopts a substantially similar *de facto* mandate, directing that "[o]ther standing

Departmental policies, procedures, and processes regarding immunization remain in effect," which includes "the ability of commanders to consider, as appropriate, the individual immunization status of personnel in making deployment, assignment, and other operational decisions …" Ex. 1, Jan. 10, 2023 Secretary Austin Rescission Memo, at 2. The Armed Services' implementing orders also retain existing restrictions and *de facto* mandates.

108. The February 24, 2023 Guidance Memo purports to prohibit new vaccination requirements and would require the Services to obtain formal DOD approval to take vaccination status into account in making assignment, deployment and operational decisions.

109. Based on Plaintiffs' review of Defendants' March 17, 2023 filing, Secretary Austin's new *de facto* mandate remains in place for all Armed Services.

110. The Army, Air Force, Marine Corps and National Guard Rescission Orders are silent and do not prohibit these Services from taking vaccination status into account in making assignment, deployment and operational decisions.

111. The Navy is the only Service that addresses this guidance, which unequivocally directs commanders to consider a Navy servicemember's vaccination status for operational decision-making purposes despite the language on the face of the policy.

112. Paragraph 3 of NAVADMIIN 038/23 states that "COVID-19 vaccination status shall not be a consideration in assessing individual service member suitability for deployment or other operational missions," but goes on to affirm that commanders "retain the authority to implement Health Protection Measures" like vaccination requirements "at any time or manner deemed necessary …" ECF 135-2 at 6-7.

113. Navy Commanders are directed to use the NAVADMIN 038/23's "COVID-19 Operational Risk Management Matrix" in making deployment decisions. *See* NAVADMIN

038/23, ¶ 2; matrix available at: https://media.defense.gov/2023/Feb/13/2003160523/-1/-1/0/BUMED%20NAVY%20COVID19%20OPERATIONAL%20RISK%20MATRIX.PDF. Notably, five of the risk factors (or nearly half of the 13 total) for making deployment decisions explicitly consider the vaccination status of personnel, and give commanders the unfettered discretion to "emphasize specific risk factor(s)" like vaccination status. *Id.*

114. As of March 24, 2023, one month after the issuance of the February 24, 2023 Guidance Memo, the DOD has not published the revised version of DODI 6205.02 implementing the requirement that the Armed Services must obtain DOD formal approval to adopt any new vaccination requirements or to take vaccination status into account in in making assignment, deployment and operational decisions.

115. The February 24, 2023 Guidance Memo expressly declines to overrule or supersede Secretary Austin's January 10, 2023 Rescission Memo. To the extent there is any conflict "or any doubt, the Secretary's directive controls. See 10 U.S.C. § 113; 10 U.S.C. § 8013(b)." February 24, 2023 Guidance Memo at 2.

116. Plaintiffs and class members continue to face a credible threat of involuntary discharge and even criminal prosecution for past violations of the now-rescinded mandate.

117. This threat is neither abstract nor speculative, as demonstrated by the testimony of Under-Secretaries from the DOD and Armed Services at a February 28, 2023 hearing before the House Armed Services Committee ("HASC"). *See* Ex. 14, Partial Hearing Transcript; full video available at: https://www.youtube.com/watch?v=TRSZsKt5j_0 and full transcript without timestamps available at: https://www.navy.mil/Press-Office/Testimony/display-testimony/Article/3315887/house-armed-services-subcommittee-on-military-personnel-holds-hearing-on-covid/.

118. There, the Under-Secretaries repeatedly confirmed that the military deems the service members who did not comply with the now-rescinded mandate to have disobeyed a lawful order for which they may be involuntarily discharged, without regard to their sincerely held religious objections. *See id.* at 2-3 (Chairman Banks questions and answers) & 5-7 (Rep. Gaetz questions and answers).

119. Defendants have refused to rule out criminal prosecution for violations of either Article 90 or Article 92 of the Uniform Code of Military Justice ("UCMJ") for those who did not file some form of accommodation. *See id.* at 3 (Army Under-Secretary Camarillo at 31:00 discussing UCMJ prosecution). The statute of limitations on Art. 90/92 charges is five years, *see* 10 U.S.C. § 843, so Plaintiffs will continue to face a credible threat of prosecution for years to come.

120. The DOD and Service Under-Secretaries also confirmed that the military has no plans or procedures to reinstate discharged service members or to provide take specific corrective actions for current members, *see id.* at 4-5, 40:55-41:18, who must pursue the existing remedies that failed them before and that several courts have found to be futile and/or inadequate. *See also* Ex. 15, DOD Under-Secretary Cisneros Feb. 27, 2023 Response to HASC, at 3.

121. Secretary Austin's memo and the Armed Services implementing orders direct the Services to "update the records" of service members to "remove any adverse actions" resulting from non-compliance. Ex. 1, Jan. 10, 2023 Secretary Austin Rescission Memo, at 1. The scope of required corrective actions is undefined.

122. Defendants have not taken corrective actions for Plaintiffs to date or committed to take corrective actions in the future.

123. There is no reason to believe that Defendants will take corrective actions in the

future because Defendants insisted throughout this litigation that no Plaintiff has been subject to adverse actions for non-compliance, and they dismiss Plaintiffs' sworn declaration attesting to the injuries suffered from such adverse actions as mere "speculation about what *might* happen in the future." ECF 14, July 15, 2022 DF PI Opp. at 19 (emphasis in original).

124. Military Defendants have not rescinded related and unlawful vaccination policies and regulations, in particular, the DOD Interchangeability Directives, which remain in full force and continue to be deemed lawful directives.

IV. FEDERAL LAWS GOVERNING LICENSING AND EMERGENCY USE AUTHORIZATION OF DRUGS AND BIOLOGICS

A. FDA Licensing of Drugs and Biologics

125. A vaccine is both a drug and a biological product and is therefore subject to regulation under both the Food, Drug, and Cosmetics Act ("FDCA"), *see* 21 U.S.C. § 321(g), and the Public Health Safety Act ("PHSA"). *See* 42 U.S.C. § 262(i)(1). The FDCA prohibits anyone from introducing or delivering into interstate commerce any "new drug" or "biological product" unless and until the FDA has approved the drug as safe and effective for its intended use. 21 U.S.C. § 331(a).

126. The biologics application addresses not only the safety and efficacy of the product, but also covers specific labeling and manufacturing requirements, including the manufacturing location, process, and storage requirements. The PHSA requires that a biologics manufacturer demonstrate that the biologic: (1) is "safe, pure, and potent" (where "potent" is equivalent to "effective" under the FDCA); and (2) that "the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent." 42 U.S.C. §262(a)(2)(C).

B. "Interchangeable" Biological Products under the PHSA

127. "Interchangeable" and "interchangeability" are specifically defined terms in Section 351 of the PHS Act, 42 U.S.C. § 262, in relation to a "reference product," which is a biological product licensed under Section 351(a) of the PHSA. 42 U.S.C. § 262(a). For the purposes of determining "interchangeability," the "reference product" must be an FDA-licensed product, *e.g.*, FDA-licensed COMIRNATY® or SPIKEVAX®. But the "interchangeable" product, the unlicensed EUA product, must be the subject of a later filed "abbreviated" application under 42 U.S.C. § 262(k).

128. Neither Pfizer/BioNTech nor Moderna filed an application with the FDA for an interchangeability determination for their COVID-19 vaccines.

129. The FDA did not make a statutory interchangeability determination.

C. Emergency Use Authorization Laws and Differences Between EUA and FDA-Licensed Products

130. The FDA may issue an EUA for a medical drug, device, or biologic, where it determines that there are no adequate, approved, and available alternatives. *See* 21 U.S.C. § 360bbb-3. There are significant differences between licensed vaccines and those subject to EUA that render them "legally distinct." ECF 4-7, August 23, 2021 Pfizer/BioNTech EUA Reissuance, at 2 n.8.

131. First, the efficacy showing is much lower for EUA products than for licensed products. EUAs require only a showing that, based on scientific evidence "if available," "it is reasonable to believe," the product "may be effective" in treating or preventing the disease. 21 U.S.C. §360bbb-3(c)(2)(A).

132. Second, the safety requirements are minimal. FDA need only find that the "known and potential benefits … outweigh the known and potential risks" of the product, considering the risks of the disease. 21 U.S.C. §360bbb-3(c)(2)(B).

133. Third, EUA products are exempt from certain manufacturing and marketing standards, enjoy broader product liability protections, and cannot be mandated due to informed consent laws and regulations.

D. Informed Consent Requirements for EUA Products

134. The FDA's grant of an EUA is subject to informed consent requirements to "ensure that individuals to whom the product is administered are informed" that they have "the option to accept or refuse administration of the product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). The FDA imposes and enforces the "option to accept or refuse" condition by requiring distribution to potential vaccine recipients a Fact Sheet that states, "It is your choice to receive or not receive [the vaccine]."

135. The FDCA directs that the FDA "shall … ensure that the individuals to whom the product is administered are informed … of the option to accept or refuse administration of the product …" 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), including the EUA Factsheet informing potential recipients that they have the "the option to accept or refuse administration of the product."

E. Labeling and Misbranding of FDA-Regulated Products.

136. The PHSA includes detailed requirements for the labeling for biologics.

> *No person shall* introduce or deliver for introduction into commerce any biological product unless –
>
> (A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and
>
> (B) each package of the biological product is plainly marked with –
>
> (i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the product; and

(iii) the expiration date of the biological product.

42 U.S.C. §262(a)(1).

137. Failure to comply with these mandatory statutory labeling requirements renders a biologic to be misbranded, which is a crime under both the FDCA and the PHSA. *See, e.g.,* 21 U.S.C. §352(a)(1) ("A drug or device shall be deemed to be misbranded… [i]f its labeling is false or misleading in any particular.").

138. The misbranding statute also prohibits false or misleading use of a licensed product's proprietary name, misrepresentations that an unlicensed product is licensed, failure to include required information on the label, or violations of any FDA regulations thereunder. *See* 21 U.S.C. § 352(e)-(g), (i), (p); 42 U.S.C. §262(b) (criminal penalties and fines for falsely labeling or altering label or packaging).

139. FDA regulations specifically prohibit "[a]ny representation that creates an impression of official approval" of an unapproved product. 21 C.F.R. § 607.39; 21 C.F.R. § 207.77(a); *see also* 21 C.F.R. § 207.77(b) ("Any representation that creates the impression that a drug is approved or is legally marketable … is misleading and constitutes misbranding."). A drug may also be misbranded is a "false or misleading representation with respect to another drug …" 21 C.F.R. § 201.6, such as an unlicensed product claiming to have the "safety" and "efficacy" findings of a licensed drug.

V. FDA INTERCHANGEABILITY GUIDANCE AND FDA WAIVERS

A. FDA Interchangeability Guidance

140. On August 23, 2021, the FDA approved the Biologics License Application ("BLA") for Pfizer/BioNTech's original "Purple Cap" formulation of COMIRNATY®. *See* FDA,

Aug. 23, 2021 Purple Cap COMIRNATY® BLA Approval Letter at 1-2, available at: https://www.fda.gov/media/151710/download (last accessed Mar. 15, 2023).

141. Also on August 23, 2021, the FDA re-issued the EUA for the Pfizer COVID-19 vaccine. *See* ECF 4-7, Aug. 23, 2021 Pfizer/BioNTech EUA Re-Issuance Letter. In a footnote, the FDA stated that the unlicensed EUA product could be used "interchangeably" with the licensed "without presenting any safety or effectiveness concerns." *Id.* at 2 n.8. The FDA acknowledged that the two products were "legally distinct", but asserted that the "differences … do not impact safety or effectiveness." *Id.*

142. On January 31, 2022, the FDA approved the BLA for Moderna's SPIKEVAX® COVID-19 vaccine. *See* FDA, Jan. 31, 2022 SPIKEVAX® BLA Approval Letter, available at: https://www.fda.gov/media/155815/download (last accessed Mar. 15, 2023).

143. Also on January 31, 2022, the FDA re-issued the EUA for Moderna's unlicensed COVID-19 vaccine because the FDA-licensed product not available in sufficient quantities. Ex. 16, Jan. 31, 2022 Moderna EUA Re-Issuance Letter. The Moderna EUA letter similarly acknowledged that the FDA-licensed SPIKEVAX® and EUA product were "legally distinct" and asserted that the unlicensed Moderna EUA COVID-19 vaccine "can be used interchangeably" with the FDA-licensed SPIKEVAX®. *See id*. at 3 n.9.

B. FDA Waivers and Enforcement Discretion

144. The FDA implemented the statutory requirement to provide recipients the "option to accept or refuse" by requiring that FDA's "Fact Sheet for Recipients and Caregivers" be made available to every potential vaccine recipient. Each Fact Sheet includes the statement that the recipient "has the option to accept or refuse" the product. *See* Aug. 23, 2021 Pfizer/BioNTech

EUA Fact Sheet at 9, available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines.

145. Peter Marks, the Director of the FDA's Center for Biologics Evaluation and Research ("CBER"), has submitted testimony stating that the FDA determined that EUA and FDA-licensed products are "medically" interchangeable, *see* Ex. 17, Oct. 21, 2022 Marks Decl., ¶ 10, but did not make a statutory interchangeability determination under the PHSA, and acknowledged the "legal distinctions" between the product categories with respect to labeling and manufacturing site approval. *Id.*, ¶ 11.

146. Dr. Marks further stated that the FDA has used its enforcement discretion to waive mandatory statutory labeling and informed consent requirements that apply to EUA products. *See Id.*, ¶ 13 ("FDA is exercising its enforcement discretion with respect to certain labeling requirements, in that FDA is not taking enforcement with respect to vials that bear the EUA label," and not requiring providers to provide "the Fact Sheet for Recipients, which advises recipients that 'under the EUA, it is your choice to receive or not receive the vaccine.'").

VI. PLAINTIFFS HAVE STANDING AND PRESENT JUSTICIABLE CLAIMS.

147. One of the named plaintiffs in this action is the unincorporated association Members of the Armed Forces for Liberty (MAFL). The members of MAFL are (a) members of the military departments of the DOD (i.e. not the Coast Guard) who were subject to the military mandate, and (b) suffered adverse consequences for refusal to take the mRNA Covid-19 vaccines for any reason recognized by law, including federal statutes and/or DOD regulations.

148. All of the named Plaintiffs have already faced, and continue to face, adverse employment or disciplinary actions, up to and including involuntary separation or discharge for violations of Art. 92; forced retirement or constructive discharge; denial of promotions,

assignments, professional schools necessary for advancement, and/or permanent change of station ("PCS") required to move to next duty assignment; negative performance evaluations; letters of reprimand or counseling; severe restrictions on personal liberty and travel; loss of retirement and other benefits, damage to their professional reputations, and diminished veterans benefits and civilian employment prospects resulting from a general discharge or "misconduct" re-enlistment code. *See, e.g.*, Ex. 5, Saran Declaration.

149. There are 744 Members of MAFL, 14 of which are the specifically named plaintiffs. Of the 744 Members of MAFL, 426 are in the Air Force, 76 are in the Navy, 88 are Marines, 157 are in the Army, and 4 are members of the Space Force. *Id*., ¶ 5.

150. Of the 426 Air Force service members of MAFL, at least 14 still have negative paperwork remaining on their records. As an example: "Major Gwilt's Individual Medical Readiness (IMR) report shows that he has a 'Covid-19 Admin Refusal' added on January 23, 2023, *after* the rescission of the mandate in the NDAA. A servicemember's IMR indicates their ability to deploy and/or attend training events, schools, etc." *Id.* ¶ 6.

151. Of those 14 cases, at least seven have negative paperwork resulting in loss of promotion. 1st LT Monteleone was set to promote to Captain on February 21st after it was delayed due to receiving a Letter of Reprimand, however, the Air Force has refused to promote him. His command states they have no idea when his paperwork will clear and when he'll be able to be promoted. At the time he was given his LOR, he was also subject to biweekly Covid EUA testing because he was unvaccinated. He still has the LOR, an Unfavorable Information File, and a Referral Officer Performance Report.

152. At least 3 members have not been reimbursed for housing and storage expenses accrued from their PCS orders being cancelled mid-travel, due to their unvaccinated status.

153. Of the 76 Navy Plaintiffs, at least one, Plaintiff Zentgraf, was separated with a JKQ separation code, which is "misconduct commission of a serious offense" and an RE-4 reenlistment code, making him ineligible to join any reserve or other branch, despite his submission of a religious accommodation request. *Id*.

154. Of the 157 Army Plaintiffs, at least 6 have flags or GOMORs on their records, making them ineligible for favorable actions, schools, promotions, etc. Of the 88 Marine Plaintiffs at least 3 have page 11s stating that they failed to obey a lawful order by not receiving the Covid-19 vaccine. All three Marines stated that the damage done to their careers is irrevocable.

155. Of the 744 punitive plaintiffs, at least 50 have received negative paperwork for refusing to test in the form of LORs, LoCs, and other negative counselings for refusing biweekly testing of the unvaccinated.

156. Of the 744 punitive plaintiffs, approximately five have been discharged and/or separated since the start of litigation.

157. During the summer of 2022, prior to each particular service injunction being granted in federal courts, dozens of members of Members of plaintiffs across various services, were given the following options, frequently on five days notice: (1) report to medical to receive the shot; or (2) refuse to report to medical and be discharged involuntarily, and therefore lose retirement benefits, for either violation of Art. 92 or being deemed non-deployable; or (3) sign a request for *voluntary* retirement (a "Retirement in Lieu of Discharge" or other equivalent paperwork). Many still had Religious Accommodation Requests pending and were told the requests would be denied even before they were given the official denial or even were availed of the appeals process. As a result, at least 20 plaintiffs were "voluntarily" retired from the military through the course of litigation, ending their careers much earlier than intended.

158. Moreover, many more Plaintiffs had already commenced the separation process and would have been involuntarily separated or discharged if the process had not been halted by the nation-wide, class injunctions enjoining the Air Force, Marine Corps and Navy from involuntarily separating unvaccinated service members who had filed a religious accommodation request.

159. Further, Plaintiffs have objected to the mandate based on the unavailability of Comirnaty, but have faced disciplinary action or involuntary separation for their refusal to take an unlicensed experimental mRNA treatment. Named Plaintiff Steven Brown ETS'd because he could not be promoted, receive any favorable actions, or reenlist and the GOMOR he received remains in his record.

160. Exhaustion is not required for Plaintiffs' APA claims. In any case, there are there are no military administrative procedures for challenging generally applicable rules or regulations issued by Secretary Austin or a Service Secretary. Nevertheless, each Plaintiffs has pursued available military remedies by submitting a Religious Accommodation Request; at least nine have had their appeals denied (or discharged before they could appeal), and several have appeals pending.

161. Most Plaintiffs have pursued religious accommodation requests. While this Complaint does not include any claims that Plaintiffs have under the Religious Freedom Restoration Act ("RFRA") or other violations of their religious liberties, more than 450 of the named Plaintiffs and MAFL members have submitted religious accommodation requests ("RAR") that have been uniformly denied.

162. Several Plaintiffs have been denied medical exemptions to which they are clearly, medically entitled under regulations currently in force regarding natural immunity and other

conditions. *See* ECF 3-4, Brown Decl., ¶11 (denied medical exemption for lack of vaccine supply); ECF 4-6, Gibson Decl., ¶ 7 (Medical exemption request never responded to, nor was the second ME request, despite doctor's concurrence with exemption); ECF 3-6, Groothousen Decl., ¶¶ 8-12 (permanent ME denied despite history cancer, Bell's palsy, migraines and high blood pressure and temporary ME for participating in clinical trial withdrawn); ECF 3-5, Wilson Decl., ¶ 7 (ME despite documented allergy to vaccine, recommendation from two doctors and previous documented infections).

VII. CLASS ACTION ALLEGATIONS.

163. Plaintiffs bring this action on their own behalf and as a class action as representative parties on behalf of all members of the class and subclasses defined herein under the provisions of Federal Rules of Civil Procedure (the Rules) 23(a) and 23(b). Plaintiffs seek declaratory and injunctive relief, and relief incident to and subordinate to it, including costs and attorney fees. A class action is appropriate because, as shown below: (a) the class is so numerous that joinder of all members is impracticable, (b) there are questions of law and fact common to the class, (c) the claims of the Plaintiffs are typical of the claims of the class, and (d) the representative parties will fairly and adequately protect the interests of the class.

164. **Definition of the Class.** The class represented by Plaintiffs in this action, and of which Plaintiffs are themselves members, consists of all members of the United States Armed Forces, including active-duty, reserves and National Guard, who were subject to the Military Mandates and who remain subject to any post-Rescission requirements, restrictions, or threat of enforcement or punishment for past violations, without regard to whether or not they sought exemption from the now-rescinded mandates.

44. **Natural Immunity Sub-Class.** Plaintiffs also include the sub-class of service

members are those who have had COVID yet been denied exemption from receiving the vaccine because of natural immunity, a decision contrary to the DoD policy expressed in all Services' vaccine regulations, AR 40-562, as well as the weight of scientific evidence.

Plaintiffs Satisfy FRCP Rule 23(a)

45. **Numerosity.** The exact number of the class and subclasses identified above is not known at this time, but the Defendants have that information. There are XX named Plaintiffs, and Plaintiffs estimate that there are thousands of class members. The class is so numerous that joinder of individual members in this action is impractical.

46. **Commonality.** There are common questions of law and fact involved in this action that affect the rights of each member of the class and the relief sought is common to the entire class. The specific claims of Plaintiffs and similarly situated class members are detailed below in the First through Fifth Causes of Action.

47. **Plaintiffs' Claims Are Typical of the Proposed Classes.** The claims of the Plaintiffs, who are representatives of the class, are typical of the claims of the class in that the claims of all members of the class, including Plaintiffs, depend on a showing of the Defendants' acts and omissions giving rise to the Plaintiffs' right to the relief sought. There is no conflict between any individual named Plaintiff and other members of the class with respect to this action, or with respect to the claims for relief set forth in this complaint. The class has similar injuries flowing from the Defendants' unlawful and unconstitutional actions.

48. The named Plaintiffs are the representative parties for the class, are able to and will, fairly and adequately protect the interests of the class. The Plaintiffs' declarations in show they adequately represent the various statuses of the class, *i.e.*, all Services, active, reserve, National Guard. The attorneys for Plaintiffs are actively pursuing Plaintiffs' case and can be responsible

for the class' interests. The named Plaintiffs and their undersigned counsel will fairly and adequately protect the interests of the class and undersigned counsel collectively have significant experience with the legal issues presented and handling them in the context of class litigation.

Plaintiffs Satisfy FRCP Rule 23(b)

49. **Definition of the Class**. The class represented by Plaintiffs in this action, and This class action is maintainable under Fed. Rule of Civil Procedure 23(b) because it satisfies the prerequisites of Rule 23(a) and the following conditions of Rule 23(b):

> (1) the prosecution of separate actions by individual members of the class would create a risk of :
>
> (A) inconsistent or varying adjudications with respect to individual members of the class that would establish incompatible standards of conduct for the Defendants, all of whom oppose the class; or
>
> (B) adjudications with respect to individual members of the class which would, as a practical matter, be dispositive of the interests of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests; and/or
>
> (2) the party opposing the class has acted and refused to act on grounds generally applicable to the class, as more specifically alleged below, on grounds which are generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole which this action seeks.

50. The findings required by Rule 23(b)(1) and (2) are supported by the fact there is a large class of chaplains against whom the Secretary and the Armed Forces have operated in a systematic discriminatory manner violating the Constitution, federal statutes, and the Defendants' own regulations. The declaratory and injunctive relief sought will affect all persons who have experienced the alleged retaliation discrimination. Furthermore, the constitutional and federal questions Plaintiffs raise dominate this action and apply to all members of the class. If Plaintiffs are successful, any individual relief that is incidental to this action will be determined by statute

and require little if any involvement by the Court. Additional considerations that support certification under 23(b)(1) and/or 23(b)(2) include:

a. Inconsistent or varying adjudications with respect to individual class members could subject Defendants to incompatible standards of conduct;

b. The Court's adjudication of the claims raised herein on behalf of the Named Plaintiffs alone would, as a practical matter, be dispositive of the interests of the other members not party to such individual adjudications and could leave those other members without the ability to protect their own interests;

c. The Defendants have acted or refused to act on grounds that apply generally to all members of the proposed Classes such that final injunctive or declaratory relief would be appropriate respecting each of the proposed Classes; and finally,

d. The issues here are primarily constitutional and statutory which involve no exercise of military discretion or expertise.

FIRST CAUSE OF ACTION
POST-RESCISSION ORDERS AND POLICIES VIOLATE 2023 NDAA
2023 NDAA § 525 & 5 U.S.C. §§ 706(2)(C)

165. Plaintiffs reallege the facts regarding Plaintiffs and those set forth in Sections II, III VI, and VII as if fully set forth in this Count.

166. Military Defendants' generally applicable post-Rescission orders and policies retaining existing restrictions (or reenacting substantially similar, a *de facto* mandate or restrictions), continuing to enforce pre-Rescission requirements and punish past violations, and refusal to restore the pre-Mandate *status quo* are actions "in excess of statutory jurisdiction [and] authority," 5 U.S.C. § 706(2)(C), because these actions directly contravene Congress' directive to rescind the August 24, 2021 mandate.

167. In Section 525 of the 2023 NDAA, Congress exercised its "plenary authority" to raise and "Regulat[e]" the military forces under Article I, Section 8, clauses 12-14 of the U.S. Constitution, *Chappell v. Wallace*, 462 U.S. 296, 301 (1982), by directing Secretary Austin to "rescind" the August 24, 2021 mandate. President and Commander-in-Chief Biden signed that directive into law on December 23, 2022.

168. "Rescind" means "an annulling; avoiding, or making void; abrogation; rescission", while "rescission" means "void in its inception"; or "an undoing of it from the beginning." BLACK'S LAW DICTIONARY at 1306 (6th ed. 1990).

169. Congress chose this term to direct Military Defendants and the courts to apply the rescission with full retroactive effect to eliminate any legal basis for the Military Mandates and any order issued pursuant thereto and to restore Plaintiffs and other Service Members to the position in which they would have been in the absence of the unlawful DOD Mandate and implementation orders.

170. Rescission further requires the Military Defendants to restore the pre-Mandate *status quo* and return service members substantially to the position in which they would have been but for the unlawful mandates. *See, e.g., Ehrlich v. United States*, 252 F.2d 772, 776 (5th Cir. 1958).

171. Congress' directive means that the Military Mandates and all orders issued pursuant thereto are now a legal nullity; are not lawful orders; can no longer be enforced; and cannot be used as the basis for discharge, separation, punishment, prosecution, or taken into consideration for any purpose.

172. Where, as here, Congress has exercised its plenary authority to raise and regulate military forces under Article I, Section 8, cl. 12-14, and it has expressly directed a specific action

and remedy—rescission—Congress has eliminated any scope for military discretion and the questions before the Court are purely matters of statutory interpretation without deference to military expertise.

173. Secretary Austin and the Military Defendants have formally rescinded the mandates. However, in the very document rescinding the mandates, Secretary Austin directs that "[o]ther standing Departmental policies, procedures, and processes regarding immunization remain in effect," which includes "the ability of commanders to consider, as appropriate, the individual immunization status of personnel in making deployment, assignment, and other operational decisions …" Ex. 1, Jan, 10, 2023 Rescission Memo, at 2.

174. Even with a service-wide injunction in place prohibiting punishment or discharge, such broad, sweeping language "allow[s] the [military] to do just about anything it wants short of punishing [Plaintiffs] and drumming them out of service," *Austin v. U.S. Navy Seals 1-26*, 142 S. Ct. 1301, 1305–06 (2022) (Alito, J., dissenting).

175. The February 24, 2023 Guidance Memo purports to eliminate remaining restrictions; to prohibit commands from considering vaccination status in making assignment, deployment, and operational decisions; and to revise DODI 6205.02 to bar the imposition of new restrictions without formal DOD approval.

176. The Army, Air Force and National Guard have not adopted any such limitation on their authority, while the only Service that has, the Navy, unequivocally directs commanders to consider vaccination status in making deployment decisions. *See supra* ¶¶ 111-113. DOD does not appear to have revised DODI 6205.02. Because Secretary Austin's January 10, 2023 directive "controls" if there is any conflict or ambiguity, February 24, 2023 Guidance at 2, Secretary Austin's *de facto* mandate remains in place.

177. On February 28, 2023, Military Defendants repeatedly affirmed to Congress that they will ignore Congress' directive and statutory rescission by maintaining that the mandates and orders issued pursuant thereto are lawful orders, despite the elimination of the legal basis therefor; that service members who have not complied with the now-rescinded mandates have disobeyed a lawful order in violation of the UCMJ; that currently serving unvaccinated service members may still be discharged or punished under the UCMJ; and that they will not require service members discharged or forced into retirement will not be reinstated or compensated. *See supra* ¶¶ 117-120; Ex. 14, Partial Transcript of Feb. 28, 2023 HASC Hearing.

178. Military Defendants have unequivocally confirmed that they have adopted a generally applicable policy not to restore the pre-Mandate *status quo* or return Plaintiffs or other service members to the position in which they would have been absent the unlawful mandate. In particular, Military Defendants will not require reinstatement of those discharged or forced into retirement; provide backpay or other compensation; convene selection boards to retroactively promote those selected for, but denied promotions due to unlawful mandates; or correct other career-ending or career damaging actions. *See generally* Ex. 14, Partial Transcript of Feb. 28, 2023 HASC Hearing; Ex. 15, Cisneros Feb. 27, 2023 Response to HASC, at 3.

179. Secretary Austin and the Military Defendants have stated that they will take corrective actions for adversely affected service members, but to date have not taken corrective action to restore Plaintiffs to the position in which they would have been absent the unlawful mandates.

180. There is no reason to believe that Defendants will take corrective actions in the future because Defendants insisted throughout this litigation that no Plaintiff has been subject to adverse actions for non-compliance, and they dismiss Plaintiffs' sworn declaration attesting to the

injuries suffered from such adverse actions as mere "speculation about what *might* happen in the future." ECF 14, July 15, 2022 DF PI Opp. at 19 (emphasis in original).

181. As a result of Defendants' unlawful actions, Plaintiffs have already suffered forced retirement, adverse personnel actions, and deprivation of religious liberties, and those who continue to serve face the credible threat of involuntary discharge, punishment under the UCMJ and loss of retirement and other benefits. Ex. 5, Saran Decl.

SECOND CAUSE OF ACTION
POST-RESCISSION MANDATES ARE ARBITRARY AND CAPRICIOUS
5 U.S.C. §§ 706(2)(A)

182. Plaintiffs reallege the facts regarding Plaintiffs and those set forth in Sections II, III VI, and VII as if fully set forth in this Count.

183. The Military Defendants' generally applicable post-Rescission orders and policies retaining pre-Rescission restrictions (or reenact a substantially similar *de facto* mandates or restrictions), continuing to enforce pre-Rescission mandates and punish service members for past non-compliance, and refusing to restore the pre-Mandate *status quo* must be set aside as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

184. In Section 525 of the 2023 NDAA, Congress and the President directed Secretary Austin to rescind the mandate. Rescission eliminated any legal basis, governmental interest, or military discretion to continue to impose or enforce the rescinded mandates, to punish service members for non-compliance, or not to restore the pre-Mandate *status quo*.

185. Congress has directed that the Military Defendants take specific actions and provide a specific remedy, namely, rescission. Congress' directive eliminated any scope for military discretion or judicial deference to military judgments.

186. Military Defendants have failed to implement Congress' directive and have therefore abused their discretion and acted contrary to law, namely, the 2023 NDAA for the reasons set forth in the First Cause of Action. *See supra* ¶¶ 166-181.

187. Military Defendants' post-Rescission orders are arbitrary and capricious, an abuse of discretion, and otherwise contrary to law for the following additional reasons.

188. First, Military Defendants' post-Rescission orders and continued enforcement of the August 24, 2021 mandate is contrary to law because it violates the DOD's own vaccination regulations, DODI 6205.02, which is the sole legal authority cited in Secretary Austin's August 24, 2021 memo, *see* ECF 4-12, Aug. 24, 2021 SECDEF Memo, at 1. The mandated, FDA-licensed COMIRNATY® and SPIKEXVAX® products are not and were not "vaccines" as that term is defined in the DOD's immunization regulation, DODI 6205.02, because these mRNA products do not include a single molecule of the COVID-19 virus. *See supra* ¶ 64.

189. Second, the post-Rescission orders and continued enforcement of the August 24, 2021 mandate is contrary to the current scientific consensus that the mandated, FDA-licensed vaccines are obsolete, ineffective, and cannot prevent transmission or infection by the Omicron variant; the guidance and actions of the expert public health agencies, the CDC and HHS; the business judgment of manufacturers who have long recognized their obsolescence and appear to have ceased production of these products one year ago; and judicial findings that the Military Defendants have not provided current, post-Omicron scientific evidence supporting the efficacy of the mandated vaccines. *See supra* ¶¶ 88-94.

190. Third, Military Defendants' generally applicable post-Rescission orders and policies to continue enforcement of the Military Mandates are arbitrary and capricious because compliance was impossible due to the unavailability of the mandated products.

191. The original Purple Cap COMIRNATY®, the product that was the proximate cause of and provided the sole legal basis for the mandate, apparently was never produced and the FDA withdrew its marketing authorization on the same day it was approved. *See supra* ¶ 78.

192. The first so-called doses of Grey Cap COMIRNATY® were not even manufactured until at the earliest January 2022 and were not acquired until June 2022, long after all applicable vaccination deadlines had passed and after Military Defendants had constructively discharged, commenced separation proceedings, ordered Boards of Inquiry, punished and taken other adverse actions against Plaintiffs and other service members.

193. The supply of "Comirnaty-labeled" vaccines that they did obtain was in fact unlicensed, misbranded EUA vaccines from the FW Lots, which Defendants subsequently acknowledged were not licensed. Defendants continued to mandate these unlicensed, EUA vaccines from the FW Lots for months after they expired in September or October 2022. *See supra* ¶¶ 79-83.

194. SPIKEVAX® was not available, in any quantity, until September 2022 at the earliest, and all available lots had expired as of the date the mandate was rescinded. *See supra* ¶ 84.

195. Finally, the Military Defendants have refused to comply with Congress' rescission directive by restoring Plaintiffs and other service members to the pre-Mandate *status quo* or return them to the position in which they would have been absent the unlawful mandates.

196. Congress' directive leaves no room for discretion or deference with respect to the remedy. Military Defendants' express refusal to comply is necessarily arbitrary to and capricious, an abuse of discretion, and contrary to Section 525 of the 2023 NDAA.

197. As a result of Defendants' unlawful actions, Plaintiffs have already suffered forced retirement, adverse personnel actions, and deprivation of religious liberties, and those who

continue to serve face the credible threat of involuntary discharge, punishment under the UCMJ and loss of retirement and other benefits.

THIRD CAUSE OF ACTION
MILITARY EUA MANDATES VIOLATE 10 U.S.C. § 1107a
5 U.S.C. § 706(2)(C); 10 U.S.C. § 1107a

198. Plaintiffs reallege the facts regarding Plaintiffs and those set forth in Sections I-VII as if fully set forth in this Count.

199. The DOD Interchangeability Directives remain in effect post-Rescission and they constitute the legal basis, along with the now-rescinded mandates, for: mandating unlicensed, EUA products; for Military Defendants' assertion that service member who refused to take an unlicensed EUA product disobeyed a lawful order; and for any resulting discharge, punishment, or other adverse actions.

200. While Congress and the President have delegated the Secretary of Defense broad authority, they have expressly withheld in 10 U.S.C. § 1107a the authority to mandate an EUA vaccine without Presidential waiver, which Secretary Austin has neither received nor requested.

201. The DOD Interchangeability Directives are *ultra vires* actions "in excess of statutory jurisdiction [and] authority." 5 U.S.C. § 706(2)(C).

202. The DOD and the Armed Services are departments and agencies of the United States Government. As such, they are agencies created by statute, and "it is axiomatic that an administrative agency's power to promulgate legislative regulations," like the DOD Mandate, "is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208, 109 S. Ct. 468 (1988).

203. While the DOD Mandate itself states that only FDA-licensed vaccines may be mandated, *see* ECF 4-12, Aug. 24, 2021 Secretary Austin Mandate Memo, at 1, the DOD

Interchangeability Directives—Ex. 3, September 14, 2021 Pfizer/BioNTech Interchangeability Directive and Ex. 4, May 3, 2022 Moderna Interchangeability Directive—direct each Armed Service to mandate EUA products "as if" they were FDA-licensed products. The Armed Services Mandates also authorize the forced administration of EUA vaccines "as if" they were the FDA-licensed product. *See, e.g.,* ECF 1-7, Air Force Mandate, §§ 3.1.1 & 5.3.2.1; ECF 4-15, BUMED Memo 6300 (Navy Interchangeability Memo). at 1.

204. Defendant FDA has made regulatory findings that the EUA and licensed product are "legally distinct." The EUA mRNA Products are subject to the laws governing EUA products, including 10 U.S.C. § 1107a, the right to informed consent, mandatory statutory labeling requirements for unlicensed products, and numerous federal and state laws that prohibit misbranding and unfair and deceptive trade practices such as misrepresenting an unlicensed product as one licensed by the FDA.

205. The licensed products, COMIRNATY® and SPIKEVAX®, are subject to the laws governing FDA-licensed products, including entirely distinct mandatory (*i.e.*, non-waivable) statutory requirements for FDA licensure and distinct statutory regimes governing labeling, misbranding, marketing, and patient disclosures. *See generally supra* Section IV.

206. These two regulatory and labeling regimes are mutually exclusive and prohibit an unlicensed, EUA-labeled product from being an FDA-licensed product at the same time, or otherwise being granted the legal status or benefits of licensure.

207. An FDA-licensed biologic product must be labeled as such for the approved indications. *See* 42 U.S.C. § 262(a).

208. The FDCA, PHSA, and FDA regulations all address the requirements stated on the product "package", "container" or "label" of the licensed product. In particular, the PHSA directs

that "each package" of the licensed product must state the "proper name" of the licensed product "contained in the package" and the "license number of the manufacturer." 42 U.S.C. § 262(a)(1)(B)(i)-(ii). *See also* 21 U.S.C. § 352 (misbranding requirements defined in terms of contents of "label" or "package"); 21 C.F.R. Pt. 610, Subpt. G ("Labeling Standards").

209. The sole authority cited by Military Defendants—a footnote in the FDA's EUA letters that is not part of statutorily required product labeling and does not purport to constitute a "statutory" interchangeability determination—does not allow the FDA itself to override these mandatory statutory labeling requirements. Nor could this footnote grant the authority to DOD officials, or anyone else for that matter, to do so.

210. Defendants were in fact "mandating vaccines from EUA-labeled vials," *Doe #1-#14 v. Austin*, 572 F.Supp.3d 1224, 1233, 2021 WL 5816632 (N.D. Fla. 2021).

211. Military Defendants could not have implemented the mandates without using EUA products because Military Defendants did not possess any FDA-licensed products. This was not because there was "not sufficient approved vaccine available" for the entire U.S. adult population, or even service members. ECF 4-7, Aug. 23, 2021 Pfizer/BioNTech EUA Reissuance, at 5 n.9. It was because there was no FDA-approved product at all.

212. The original FDA-licensed Purple Cap COMIRNATY®, which provided the legal basis for the DOD Mandate apparently was never manufactured and the FDA withdrew its marketing authorization on the same day that it was approved. *See supra* ¶ 78.

213. The Military Defendants have further acknowledged that they did not have any FDA-licensed product, which they refer to as "Comirnaty-labeled", until at the earliest June 2022. *See supra* ¶¶ 79-83.

214. Military Defendants' administrative records filings, statements in oral arguments, and confirm that they have violated 10 U.S.C. § 1107a by mandating EUA products and treating all EUA products as legally interchangeable with the FDA-licensed product.

215. As a result of Defendants' violations of numerous federal laws and regulations, Plaintiffs have already suffered forced retirement, adverse personnel actions, and deprivation of religious liberties, and those who continue to serve face the credible threat of involuntary discharge, punishment under the UCMJ and loss of retirement and other benefits.

FOURTH CAUSE OF ACTION
MILITARY MANDATES & INTERCHANGEABILITY DIRECTIVES ARE *ULTRA VIRES*

216. Plaintiffs reallege the facts regarding Plaintiffs and those set forth in Sections I-VII as if fully set forth in this Count.

217. No federal statute authorized the mandate of unlicensed EUA products, the DOD Interchangeability Directives, or the Armed Services implementation thereof.

218. "An agency's power is no greater than that delegated to it by Congress." *Lyng v. Payne*, 476 U.S. 926, 937 (1986). Agency actions that exceed the agency's authority are *ultra vires* and must be invalidated.

219. In 10 U.S.C. § 1107a, Congress exercised its plenary authority to regulate the military forces, and protect service members' rights to informed consent by expressly prohibiting the mandate of an unlicensed EUA vaccine, except where the Secretary of Defense has requested, and receives, express written Presidential authorization to do so on national security grounds.

220. Secretary Austin did not request or receive Presidential Authorization for the COVID-19 EUA vaccines. *See Doe #1-#14*, 572 F.Supp.3d at 1235.

221. The Defense Secretary and the President are the only officials authorized to take action pursuant to 10 U.S.C. § 1107a. Neither did.

222. Accordingly, the basis for mandating unlicensed EUA products were the Pfizer/BioNTech and Moderna Interchangeability Directives, issued by Assistant Secretary of Defense Adirim and Mullen, respectively, and the respective officials in the Departments of the Army, Air Force, and Navy.

223. None of these officials and officers of the United States had any authority to mandate unlicensed EUA products in violation of 10 U.S.C. § 1107a.

224. Accordingly, each of these officials acted *ultra vires.*

225. The Military Defendants' officials and officers of the United have acted without any lawful authority whatsoever, and without any colorable basis for the exercise of authority.

226. The Armed Services implementation of the DOD Mandate, in conjunction with the DOD Interchangeability Directives, violated 10 U.S.C. § 1107a, as well as the FDCA, PHSA, and FDA labeling and misbranding regulations, for the reasons set forth above in the Third Cause of Action. *See supra* ¶¶ 199-215.

227. Where, as here, an agency or officer of the United States has acted *ultra vires* in violation of a statute or otherwise in excess of its delegated authority, or where agency action is deemed not to be final and not subject to review under the APA, a person injured by such action may assert a claim for specific relief.

228. Plaintiffs' injuries are due to the *ultra vires* actions of Military Defendants' officials and officers of the United States, which have wholly deprived them of their rights under 10 U.S.C. § 1107a, the FDCA, PHSA, and FDA labeling and misbranding regulations.

229. Military Defendants' *ultra vires* actions have and continue to inflict harm on Plaintiffs, as alleged herein.

230. Plaintiffs' *ultra vires* claims are not barred by sovereign immunity where these federal officers have acted outside the scope of their authority. *See, e.g., Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 691 & n.11 (1949).

FIFTH CAUSE OF ACTION
DOD INTERCHANGEABILITY DIRECTIVES ARE ARBITRARY & CAPRICIOUS
5 U.S.C. § 706(2)(A); DODI 6200.02

231. Plaintiffs reallege the facts regarding Plaintiffs and those set forth in Sections I-III, VI, and VII as if fully set forth in this Count.

232. The DOD Interchangeability Directives must be set aside as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), because they constitute an unannounced and unexplained departure from a prior policy and are directly contrary to the currently effective DOD regulation on EUA products, DODI 6200.02.

233. The consistent policy of the Military Defendants since the enactment of the EUA statute and 10 U.S.C. § 1107a in 2004 through at least July 2021 (*i.e.*, the month before the DOD Mandate was issued) was that EUA products may not be mandated.

234. The first vaccine that Defendant FDA ever granted EUA status to was the anthrax vaccine during the course of litigation over the DOD's anthrax vaccine mandate, where the Defendants DOD and FDA took the exact opposite legal position of their position for the COVID-19 vaccines. There, after D.C. District Court preliminarily enjoined the anthrax mandate in *Rumsfeld I*, and then granted summary judgment and a permanent injunction in *Rumsfeld II*, both the DOD and FDA jointly filed an emergency petition in the D.C. District Court to modify the permanent injunction already to allow the vaccine to be administered to servicemembers solely on a voluntary basis. *See Rumsfeld III*, 2005 WL 774857, at *1.

235. This was the Military Defendants' consistent position through at least July 6, 2021,

as set forth a July 6, 2021 memorandum from the Office Legal Counsel, the DOD interpreted the informed consent requirements in 10 U.S.C. § 1107a "to mean that DOD may not require service members to take an EUA [vaccine]" without first obtaining a Presidential Waiver under 10 U.S.C. § 1107a. *See* ECF 5-14, Office of Legal Counsel, *Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization* at 16 (July 6, 2021).

236. "[A]gencies must typically provide a 'detailed explanation' for contradicting a prior policy;" they may not, as DOD has done here, "depart from a prior policy *sub silentio*." *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 614 (5th Cir. 2021) (*quoting FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). The Military Defendants' "established practices" on informed consent are due greater deference than sudden, unexplained reversals because the long-standing and consistent refusal to exercise a claimed power (*i.e.*, to mandate an EUA product) is "significant in determining whether such a power was actually conferred." *W. Va. v. EPA*, 142 S. Ct. 2587, 2610 (2022) (citation and quotation marks omitted).

237. The DOD Interchangeability Directives and Defendants' litigation position also directly contradicts its currently effective regulations on EUA products, which have from at least 2008 through the present continuously provided a right of refusal for EUA products. *See* DOD Instruction 6200.02, § E3.4 (Feb. 27, 2008) (under the EUA statute, "potential recipients are provided an option to refuse administration," but "the President may . . . waive the option to refuse"). There has been no Presidential Waiver, yet the Defendants are mandating use of EUA vaccines.

238. As a result of Defendants' violations of numerous federal laws and regulations, Plaintiffs have already suffered forced retirement, adverse personnel actions, and deprivation of

religious liberties, and those who continue to serve face the credible threat of involuntary discharge, punishment under the UCMJ and loss of retirement and other benefits.

SIXTH CAUSE OF ACTION
FDA INTERCHANGEABILITY GUIDANCE VIOLATES FEDERAL LAW
5 U.S.C. § 706(2)(C); 42 U.S.C. § 262

239. Plaintiffs reallege the facts regarding Plaintiffs and those set forth in Sections II.B, IV,V, and VII if fully set forth in this Count.

240. The FDA acted "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," 5 U.S.C. § 706(2)(C), and contrary to law and the FDA's own rules and policies, where it found that the EUA and FDA-licensed products "can be used interchangeably" ("FDA Interchangeability Guidance"). *See* ECF 4-7, Aug. 23, 2021 Pfizer/BioNTech EUA Reissuance; Ex. 16, Jan. 31, 2022 Moderna EUA Reissuance, at 3 & n.9.

241. "Interchangeable" and "interchangeability" are statutorily defined in relation to a "reference product," which is a biological product licensed under Section 351(a) of the PHSA, 42 U.S.C. § 262(a). For the purposes of determining "interchangeability," the "reference product" must be an FDA-licensed product (*i.e.*, COMIRNATY® or SPIKEVAX®). But the unlicensed "interchangeable" product for which licensure or legally equivalent treatment is sought—here, the EUA product—must be the subject of a later filed "abbreviated" application under 42 U.S.C. § 262(k).

242. Neither Pfizer/BioNTech nor Moderna filed an abbreviated application required for an interchangeability determination under the PHSA.

243. The FDA disclaims having made a statutory interchangeability determination under the PHSA.

244. The FDA instead describes its actions as finding that the two are "medically

interchangeable", Ex. 17, Marks Decl., ¶ 11, an invented term that either has no legal significance, or if it does, explicitly contradicts the requirements of the PHSA.

245. The PHSA grants the FDA the authority only to make "statutory" interchangeability determinations, which is governed by an "intricate process," *Texas v. U.S.*, 809 F.3d 134, 179 (5th Cir. 2015) ("*Texas*"), *aff'd* 136 S.Ct. 2271 (2016), set forth by Congress in the PHSA.

246. The PHSA does not authorize the FDA to create new, alternative categories or criteria for "interchangeable" products. As such, the FDA's action must be held unlawful and *ultra vires*.

247. The FDA use of "interchangeable" and "interchangeably" is incompatible with the PHSA's statutory framework and the publicly available record. At a minimum, this Court must remand the matter to the FDA to explain its decisions. *See, e.g., A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1492 (D.C. Cir. 1995) (remanding to the FDA to explain what "bioequivalency" means in the animal drug context and how the evidence relied on by the FDA satisfied the standard).

248. The FDA's Interchangeability Guidance was included in its letters extending or modifying the EUA for the Pfizer/BioNTech and Moderna COVID-19 EUA products, but this guidance was not issued pursuant to the FDA's statutory authority to grant EUAs in the EUA statute, 21 U.S.C. § 360bbb-3.

249. The PHSA is the sole statutory authority for the FDA to make an interchangeability determination. The EUA statute does not even mention the terms "interchangeable" and "interchangeably", much less grant the FDA the authority to make such determinations under the EUA statute, or override the PHSA's requirements for doing so.

250. Because the FDA's non-statutory "interchangeability" determinations were not issued pursuant to the EUA statute, it is not an action exempt from judicial review under the EUA

statute's standard for actions "committed to agency discretion." 21 U.S.C. § 360bbb-3(i).

251. The FDA also exceeds its statutory authority, abuses its discretion, and acts contrary to law when it applies two distinct and mutually exclusive regulatory regimes to the same product. *See, e.g., Genus Med. Techs. LLC v. FDA*, 994 F.3d 631 (D.C. Cir. 2020).

252. The FDA unlawfully treated as equivalent, or "interchangeable", "legally distinct" products subject to distinct and mutually exclusive regulatory regimes.

253. The EUA mRNA Products are subject to the laws governing EUA products, including the right to informed consent in 21 U.S.C. §§ 360bbb-3 (and 10 U.S.C. § 1107a for service members); mandatory statutory labeling requirements for unlicensed products; and numerous federal and state laws that prohibit misbranding, in particular, misrepresenting an unlicensed product as one licensed by the FDA.

254. The licensed products, COMIRNATY® and SPIKEVAX®, are subject to the laws governing FDA-licensed products, including entirely distinct mandatory (*i.e.*, non-waivable) statutory requirements for FDA licensure and distinct statutory regimes governing labeling and misbranding. *See generally supra* Section IV.

255. These two regulatory and labeling regimes are mutually exclusive and prohibit an unlicensed, EUA-labeled product from being an FDA-licensed product. An FDA-licensed biologic product must be labeled as such for the approved indications. *See* 42 U.S.C. § 262(a). In particular, the PHSA directs that "each package" of the licensed product must state the "proper name" of the licensed product "contained in the package" and the "license number of the manufacturer." 42 U.S.C. § 262(a)(1)(B)(i)-(ii). *See also* 21 U.S.C. § 352 (misbranding requirements defined in terms of contents of "label" or "package"); 21 C.F.R. Pt. 610, Subpt. G ("Labeling Standards").

256. Defendants have cited no statute or any other legal authority that would allow a

footnote in an FDA letter that grants emergency use authorization—and that is not part of the product labeling—to override these mandatory statutory labeling requirements.

257. As a result of Defendants' violations of numerous federal laws and regulations, Plaintiffs have already suffered forced retirement, adverse personnel actions, and deprivation of religious liberties, and those who continue to serve face the credible threat of involuntary discharge, punishment under the UCMJ and loss of retirement and other benefits.

SEVENTH CAUSE OF ACTION
FDA WAIVERS VIOLATE MANDATORY STATUTORY REQUIREMENTS
5 U.S.C. §§ 706(2)(A) & (C); 21 U.S.C. § 352; 42 U.S.C. § 262

258. Plaintiffs reallege the facts set forth in Sections II.B, IV, V, and VII as if fully set forth in this Count.

259. The FDA's purported waiver of non-waivable mandatory statutory labeling and informed consent requirements ("FDA Waiver"), and its approval of false, misleading and deceptive product labeling that caused these products to be misbranded must be set aside as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), and "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

260. The FDA Waivers unlawfully waived nonwaivable mandatory statutory labeling requirements and prohibitions to grant the legal benefits or status of FDA licensure to unlicensed products and to wholly deprive recipients and potential recipients like Plaintiffs of their statutory informed consent right to refuse to take an EUA product.

261. To justify the FDA Waivers, the FDA has stated that it has exercised its "enforcement discretion", Ex. 17, Marks Decl., ¶ 13, not to enforce labeling requirements—or the requirement to provide the EUA factsheet that includes the "option to accept or refuse" the EUA

vaccine—so that unlicensed, EUA vaccines may be treated "as if" they were licensed vaccines and eliminating the statutory right to refuse the unwanted treatment.

262. In doing so, the FDA went far beyond permissible agency enforcement discretion, which pertains to enforcement priorities and agency inaction. Instead, the FDA's purported nonenforcement decision amounted to "affirmative acts of approval"—treating unlicensed, misbranded products as if they were licensed and labeled in accordance with FDA regulations—"rather than refusal to take enforcement action." *Cook v. FDA*, 733 F.3d 1, 7 (D.C. Cir. 2013).

263. While agencies have "law-enforcement discretion", such "discretion does not 'set agencies free to disregard legislative direction.'" *Florida v. United States*, --- F.Supp.3d ---, 2023 WL 2399883, at *25 (N.D. Fla. Mar. 8, 2023) (*quoting Heckler v. Chaney*, 470 U.S. 821, 832-33 (1985)).

264. It is not within the FDA's discretion to confer a legal benefit for a product (*i.e.*, licensure), or to exempt categories of unlicensed products from labeling requirements applicable to them, when Congress has already established an "intricate process," *Texas*, 809 F.3d at 179, governing licensure and the benefits thereof in the PHSA.

265. The same conclusion applies to the FDA's waiver of the requirement to include the EUA Factsheet advising recipients of their right to refuse the EUA product. The requirement to provide the EUA Factsheet is mandatory: the FDA "shall … ensure that the individuals to whom the product is administered are informed … of the option to accept or refuse administration of the product …" 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). The FDA cannot waive this requirement, nor may it authorize a third party—like the Military Defendants—to destroy, remove or refuse to provide to recipients the product labeling required by statute.

266. The FDA Waivers and related statutory violations, including its approval of false,

misleading and deceptive product labeling, caused these mRNA Products to be misbranded in violation of 21 U.S.C. § 352 and applicable FDA labeling regulations. *See, e.g.,* 21 C.F.R. §§ 201.1 - 201.328 (for drugs), and 21 C.F.R. §§ 610.60 - 610.68 (for biologics).

267. The FDA-approved product labeling required to be included with every package is misleading and deceptive insofar as it unlawfully asserts that the EUA and FDA-licensed products are equivalent in terms of both safety and efficacy. The EUA Factsheets for both products state that the products "can be used interchangeably … without presenting any safety or effectiveness concerns." Aug. 23, 2021 Pfizer/BioNTech EUA Factsheet at 1 n.1. This would lead the reasonable consumer to believe that the unlicensed product is equivalent to the licensed product, or that it is the licensed product, which is practically a *per se* violation of statutes and regulations prohibiting misbranding.

268. The Military Defendants have admitted that they expressly "relied" on the FDA's unlawful actions to mandate unlicensed EUA products. *See [Coker cite?]* ECF 14, July 15, 2022 DF Opp., at 25. This admission is sufficient to establish causation, redressability and traceability required for Plaintiffs to have standing to challenge the FDA actions.

269. Even if the Military Defendants' position that the EUA-labeled products are in fact licensed products were correct, then these EUA-labeled products would still be misbranded for non-compliance with the PHSA and FDCA mandatory labeling requirements, in particular, the requirement that the product label include the proprietary name (*i.e.*, COMIRNATY® or SPIKEVAX®) and license number. *See* 42 U.S.C. § 262(a)(1)(B)(i)-(ii); 21 U.S.C. §§ 352(b), (e), (f); 21 C.F.R. §§ 610.61-610.62.

270. As a result of Defendants' violations of numerous federal laws and regulations, Plaintiffs have already suffered forced retirement, adverse personnel actions, and deprivation of

religious liberties, and those who continue to serve face the credible threat of involuntary discharge, punishment under the UCMJ and loss of retirement and other benefits.

EIGHTH CAUSE OF ACTION
FDA INTERCHANGEABILITY GUIDANCE & WAIVERS ARE *ULTRA VIRES*

271. Plaintiffs reallege the facts set forth in Sections II.B, IV, V, and VII as if fully set forth in this Count.

272. No federal statute authorized the FDA Interchangeability Guidance or the FDA Waivers.

273. The FDA Interchangeability Guidance and FDA Waivers violate the Informed Consent Laws, the FDCA, PHSA, and FDA labeling and misbranding regulations.

274. "An agency's power is no greater than that delegated to it by Congress." *Lyng v. Payne*, 476 U.S. 926, 937 (1986). Agency actions that exceeded the agency's authority are *ultra vires* and must be invalidated.

275. Where an agency or officer of the United States has acted *ultra vires* in violation of a statute or otherwise in excess of its delegated authority, or where agency action is deemed not to be final and not subject to review under the APA, a person injured by such action may assert a claim for specific relief.

276. None of these officials and officers of the United States had any authority to make a finding that the FDA-licensed and EUA versions of the COVID-19 vaccines are interchangeable, without first following the procedures set forth in the PHSA.

277. None of these officials and officers of the United States had any authority to waive the mandatory requirements in 21 U.S.C. § 360bbb-3, which require that each EUA product package include the EUA factsheet and that each recipient be informed of the statutory right to refuse administration of the product.

278. None of these officials and officers of the United States had any authority to waive mandatory statutory labeling and misbranding requirements in the FDCA and PHSA or the corresponding provisions of the FDA's labeling and misbranding regulations.

279. Accordingly, each of these officials and officers of the United States acted *ultra vires*.

280. The FDA officials and officers of the United have acted and are acting without any lawful authority whatsoever, and without any colorable basis for the exercise of authority.

281. Plaintiffs' *ultra vires* claims are not barred by sovereign immunity where these federal officers have acted outside the scope of their authority. *See, e.g., Larson*, 337 U.S. at 691 & n.11 (1949).

282. Plaintiffs' injuries are due to the *ultra vires* actions of FDA officials and officers of the United States, including Peter Marks, who have wholly deprived of their rights under the Informed Consent Laws, the FDCA, PHSA, and FDA labeling and misbranding regulations.

283. Defendants' *ultra vires* actions have and continue to inflict harm on Plaintiffs, as alleged herein.

EIGHTH CAUSE OF ACTION
POST-RESCISSION ORDERS VIOLATE EQUAL PROTECTION CLAUSE U.S. CONST. AMENDS. V & XIV

284. Plaintiffs reallege the facts regarding Plaintiffs and in Sections I-III, VI, VII as if fully set forth in this Count.

285. The Equal Protection Clause prohibits legal classifications that affect equally situated groups of citizens differently than others. *See Engquist v. Or. Dept. of Agric.*, 553 U.S. 591, 601 (2008). The touchstone of this analysis is whether a state creates disparity between classes of individuals whose situations are arguably indistinguishable. *See Ross v. Moffitt* 417 U.S. 600,

609 (1974).

286. The rescinded August 24, 2021 Mandate and Military Defendants' post-Rescission orders have created two new classes of service members: (1) those who are "fully vaccinated" or "up-to-date" on vaccination (*i.e.*, primary series plus an ever-increasing number of booster shots), (2) and those who are not.

287. The Military Mandates and Military Defendants' generally applicable post-Rescission orders and policies authorize and encourage discrimination against unvaccinated service members.

288. Military Defendants were fully aware that the mandates created two classes of service members and signaled their intent to continue to discriminate against the unvaccinated post-Rescission. In early December 2022, Secretary of the Navy Carlos Del Toro stated that the proposed rescission of the mandate will "unquestionably . . . create almost two classes of citizens in our services . . . Those that can't deploy and those that can deploy." *Supra* Mongilio ¶ 99.

289. Pre-Rescission, Plaintiffs and class members were subjected to arbitrary, discriminatory and punitive adverse personnel actions and restrictions, up to and including involuntary general discharge or separation and punishment under the UCMJ, based solely on their vaccination status and non-compliance with an order that has been rescinded.

290. Military Defendants continue to insist that unvaccinated Plaintiffs and class members may be punished for "failure to obey a lawful order" under Article 92, UCMJ.

291. Military Defendants carried out these punishment and adverse actions, despite the fact that no FDA-licensed products were available, rendering compliance with the August 24, 2021 DOD Mandate impossible.

292. Military Defendants' discriminatory treatment and punishment of the unvaccinated

was further contrary to the DOD's own vaccination regulation, AR 40-562, which exempts those whom have already had infection with a virus from vaccination requirements for that same virus.

293. Military Defendants have not corrected or remedied these past and ongoing injuries.

294. Post-Rescission, Plaintiffs and class members who remain unvaccinated and failed to comply with the rescinded mandates will be deemed to have disobeyed a lawful order and will be subject to further punishment, discrimination, involuntary discharge, or even prosecution under the UCMJ.

295. Post-Rescission, commands may continue to consider taking the vaccination status of Plaintiffs and other class members into account in making assignment, deployment and operational decisions.

296. Pre-Rescission, the situations of these two classes of service members are indistinguishable with regard to the entire justification for forcing them to take the injections: fully vaccinated soldiers can and frequently do become infected or re-infected with SARS-CoV-2 and can transmit SARS-CoV-2 to fellow soldiers, just like those who are not fully vaccinated.

297. The Natural Immunity Plaintiffs' Equal Protection rights under the Fourteenth Amendment are violated by the Defendants' arbitrary, unscientific, unsupportable distinctions between Natural Immunity Plaintiffs, who have naturally acquired immunity, and other similarly situated military members who have only artificially induced immunity through mRNA injectables. The scientific evidence shows that vaccines (a) do not stop reinfection among the vaccinated, and (b) do not stop spread of the virus by the vaccinated.

298. Several courts have found that Military Defendants' pre-Rescission implementation of the Military Mandates likely systematically violated service members' religious liberties protected by RFRA and the First Amendment. *See, e.g.,* ECF 15, July 22, 2022 PL Reply Br., at

19 & n.26 (collecting cases).

299. Military Defendants' systematic violations of religious liberties demonstrate that the policy is driven by improper animus against the religious servicemembers who are have sought religious accommodation based on their sincerely held religious beliefs. Such religious discrimination based on improper animus violated the Equal Protection Clause. *See Trump v. Hawaii*, 138 S.Ct. 2392, 2420 (2018) (*quoting Dep't of Agriculture v. Moreno*, 413 U.S. 528, 534 (1973)(noting that the Court has struck down policies as illegitimate under rational basis where "a common thread has been that the laws at issue lack any purpose other than a 'bare. . . desire to harm a politically unpopular group'").

300. Congress' rescinded the mandates, eliminating any legal basis or legitimate governmental interest in differential or discriminatory treatment of the vaccinated and unvaccinated, continued enforcement of the rescinded mandates, or future punishment or prosecution for past violations or non-compliance.

301. Military Defendants' generally applicable post-Rescission orders and policies, differential treatment of the two classes, continued enforcement of the mandates, and punishment of the unvaccinated for past violations of or non-compliance with the mandates violates both 2023 NDAA and the Equal Protection Clause.

302. Military Defendants' generally applicable post-Rescission orders and policies cannot withstand rational basis review because Congress' rescission eliminated any legal basis or legitimate government interest in the retention or continued enforcement of the rescinded mandates because such continued enforcement or punishment for non-compliance is contrary to federal law.

303. Congress rescinded the Military Mandates due to their catastrophic damage to miliary readiness, retention, and recruiting that resulted in the loss of up to 100,000 service

members, roughly .

304. In rescinding the mandates, Congress rejected Military Defendants' asserted justifications, *i.e.,* military readiness, health, unit cohesion, etc. Post-Rescission, Military Defendants may not be permitted to usurp Congress' authority; Congress has spoken to the issue and rejected DOD's attempts to justify the (continued) imposition of arbitrary, discriminatory and punitive actions against "unvaccinated" service members, in comparison with those that are "fully vaccinated." Congress' rescission and Secretary Austin's Memorandum removed the mRNA Covid-19 vaccines from the list of required vaccines for military service. There is no longer any "status" to be considered with respect to those shots, whether one has taken them or not.

305. As a result of the Defendants' unlawful actions, the Plaintiffs have suffered damages, including being required to take an unlicensed drug of unknown long-term safety profile; being subject to or threatened with disciplinary action under the UCMJ, and including adverse administrative action that would characterize Plaintiffs' voluntary service as less than a full honorable discharge.

306. As a result of Defendants' violations of numerous federal laws and regulations, Plaintiffs have already suffered forced retirement, adverse personnel actions, and deprivation of religious liberties, and those who continue to serve face the credible threat of involuntary discharge, punishment under the UCMJ and loss of retirement and other benefits.

NINTH CAUSE OF ACTION
DECLARATORY AND INJUNCTIVE RELIEF
28 U.S.C. § 1331 & 28 U.S.C. § 2201

307. Plaintiffs reallege the facts regarding Plaintiffs and in Sections I-VII as if fully set forth in this Count.

308. Dozens of Plaintiffs and intervenors during the time when the *Rumsfeld I*

preliminary injunction, the *Rumsfeld II* permanent injunction, and/or the *Rumsfeld III* consent decree were in place, were beneficiaries of these protections, and may be deemed to have been parties to these proceedings.

309. The summary judgment and consent decree in the *Doe v. Rumsfeld* anthrax vaccine cases should be given preclusive effect here because those cases and the instant case involve: (a) the same Defendants (DOD and FDA); (b) the same statute, issues, and product, an unlicensed EUA product sought to be mandated; (c) these issues were fully litigated, resulting in a 2004 permanent injunction in *Rumsfeld II* against the same Defendants that was voluntarily modified pursuant to an emergency request by DOD and FDA, resulting in the 2005 *Rumsfeld III* consent decree, prohibiting mandate of EUA products or any disciplinary action against service member for refusal; (d) some of the same Plaintiffs, namely, those who were subject to anthrax mandate and covered by DOD-wide injunction and consent decree; and (e) engendered significant reliance interests for those plaintiffs.

310. Defendants DOD and FDA must be estopped from taking a contrary position here to that taken in the *Doe v. Rumsfeld* litigation, and in particular, the *Rumsfeld III* consent decree.

311. Plaintiffs seek judicial review and declaratory and injunctive relief from these actions pursuant to the inherent equity powers of the Court pursuant to 28 U.S.C. § 2201 and 28 U.S.C. § 1331.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully ask this Court to:

(1) Declare that Congress' directive to "rescind" the Military Mandates means that the August 24, 2021 DOD Mandate is null and void *ab initio*, is no longer a lawful order, and cannot provide the legal basis for any subsequent orders issued pursuant thereto;

(2) Declare that the 2023 NDAA Rescission requires that the DOD and Armed Services restore Plaintiffs and other service members to the pre-Mandate *status quo ante* and

return them to the position in which they would have been absent the rescinded mandates;

(3) Declare that vaccination orders issued pursuant to the now-rescinded mandates are not lawful orders and are instead legal nullities;

(4) Declare that Plaintiffs' non-compliance with such vaccination orders, or others based on the now-rescinded mandates, cannot constitute disobeying a lawful order or be used as the basis for discharge, punishment, or other adverse actions;

(5) Declare unlawful and enjoin any discharge, UCMJ punishment or prosecution, or other adverse personnel action taken based on violations of the now-rescinded Military Mandates;

(6) Order the Military Defendants to restore Plaintiffs to the pre-Mandate *status quo ante* and to return them to the position in which they would have been absent the unlawful mandates;

(7) Declare unlawful, vacate and enjoin the DOD Interchangeability Directives;

(8) Declare unlawful and enjoin the mandate of any EUA product without the Presidential waiver provided under 10 U.S.C. § 1107a;

(9) Declare unlawful, vacate and enjoin the FDA Interchangeability Determination;

(10) Declare unlawful, vacate and enjoin the FDA Waivers of mandatory statutory labeling and informed consent requirements; and

(11) Award attorneys' fees, costs, and any other appropriate relief in the Court's discretion.

Dated: March 24, 2023

Respectfully submitted,

/s/ Jerri Lynn Ward
Jerri Lynn Ward, Esq.
Texas Bar #20844200
Garlo Ward, P.C.
1017 Rose Circle
College Station, Texas 77840
(512) 302-1103 ext. 115
jward@garloward.com

/s/ Dale Saran
Dale Saran, Esq.
MA Bar #654781
19744 W 116th Terrace

Olathe, KS 66061
Telephone: 480-466-0369
Email: dalesaran@gmail.com

/s/ Brandon Johnson
DC Bar No. 491370
Defending the Republic
2911 Turtle Creek Blvd., Suite 300
Dallas, TX 75219
Tel. 214-707-1775
Email: bcj@defendingtherepublic.org

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

This is to certify that I have on this day e-filed the foregoing Plaintiffs' Fourth Amended and Supplemental Complaint for Declaratory and Injunctive Relief using the CM/ECF system providing service to all counsel of record.

This 24th day of March, 2023.

Respectfully Submitted,

/s/ Dale Saran
Dale Saran